

Dense Women

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Pink ribbons have become a fixture in our society. Breast cancer advocates have mobilized to bring breast cancer awareness to heights that would have been unimaginable a generation ago. Women are indoctrinated with the familiar mantra that early detection is the best protection against breast cancer. As a result, cadres of women were dismayed when diagnosed with advanced stage breast cancer despite having had their yearly prescribed mammogram. Along with their diagnosis, they were also told for the first time that they had dense breast tissue, which can obscure cancer on mammography film. Outraged and disgusted that their physicians did not disclose their breast density sooner, these dense women turned to legislators for help. Their stories are compelling. Their remedy seems obvious. If doctors are not telling their patients that they have dense breast tissue, then the law should force them to do so. Legislators across the country have listened and many have been convinced of the merits. After all, why would a legislator not support legislation that seeks to empower women and give them information to make informed choices about their healthcare? In 2009, Connecticut became the first state to enact dense breast notification legislation and since then an additional twenty-two states have followed suit. Currently, seven state legislatures and the U.S. Congress are considering breast density notification bills.

This Article presents the case against breast density notification statutes and argues that such statutes are actually injurious to women. Part II provides context by providing background about breast cancer and how it is diagnosed. Part III explores the ideal of patient autonomy and analyzes whether the enacted dense breast tissue notification statutes empower or undermine women. Part IV examines how these statutes affect patient care and calls into question the wisdom of having legislators dictating the standard of care along with the content of physician-patient communications. Part V offers a path forward by calling on states and the federal government to inform women broadly through public health initiatives instead of utilizing standardized breast density notifications. It also offers suggestions for

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legislators who prefer a statutory remedy. Finally, Part VI offers a brief conclusion.

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I. INTRODUCTION

Like the scarlet letter “A,” breast cancer used to be a blot on the escutcheon for American women.¹ Women who were diagnosed with breast cancer did not discuss their diagnosis privately or publicly.² Forty years ago, vast support networks did not exist. Millions did not Race for the Cure.³ Pink ribbons were worn at the end of pig-tails of little girls and not on the lapels of

¹ See Barbara F. Sharf, *Out of the Closet and into the Legislature: Breast Cancer Stories*, 20 HEALTH AFF. 213, 213 (2001) (discussing that prior to the 1990s women “did not disclose their personal stories of breast cancer to one another privately, let alone publicly”).

² *Id.*

³ See Holly Yan, *Tens of Thousands Expected at Race for the Cure—The Event, in Its 22nd Year, Raises Money to Fight Breast Cancer*, DALL. MORNING NEWS, Oct. 15, 2004, at 1B (noting that Dallas hosted the first Race for the Cure in 1983 with 800 people participating); see also Paul Walsh, *Olympic Champ Set to Walk in Race for the Cure*, STAR TRIB. (May 7, 2011), <http://m.startribune.com/lifestyle/health/121383414.html> [<http://perma.cc/2H4Y-HZP8>] (“The Komen Race for the Cure has grown to more than 100 races worldwide, with more than 1 million participating in 2010.”).

adults.⁴ October was mostly associated with crisp cool air and football,⁵ and the notion of NFL football players tackling each other while wearing pink cleats to raise awareness for breast cancer would have been absurd.⁶ Needless to say, there has been a profound shift in the amount of societal support for women diagnosed with breast cancer.

Prior to the 1970s, women who were diagnosed with breast cancer had very few options. They were routinely treated with a “one-step” mutilative procedure known as a radical mastectomy.⁷ Physicians, who at that time were mostly male,⁸ were quick to remove a woman’s breast upon diagnosis of cancer because many viewed the breast as a “nonvital and functionless gland.”⁹ Some physicians believed that women were prone to hysteria, overly emotional, and incapable of making rational decisions.¹⁰ As a consequence,

⁴ See GAYLE A. SULIK, *PINK RIBBON BLUES: HOW BREAST CANCER CULTURE UNDERMINES WOMEN’S HEALTH* 47 (2010) (noting that the pink ribbon was introduced as the official symbol for breast cancer awareness in 1992).

⁵ See, e.g., Leah Nurik, *I Survived Breast Cancer, but I Hate Breast Cancer Awareness Month*, WASH. POST (Oct. 10, 2014), <https://www.washingtonpost.com/posteverything/wp/2014/10/10/i-survived-breast-cancer-but-i-hate-Breast-cancer-awareness-month/> [<http://perma.cc/Q8LT-US4R>] (explaining that her love of October has been faded because of the “pervasiveness of pink ribbons”).

⁶ Currently, the NFL is known for dousing players in pink during the month of October to shore up its female fan base. See Lindsay H. Jones, *NFL Pushes on with Pink Campaign*, USA TODAY (Sept. 30, 2014), <http://www.usatoday.com/story/sports/nfl/2014/09/30/nfl-breast-cancer-awareness/16508773/> [<http://perma.cc/9V4B-V9NU>] (noting that the “NFL’s annual breast cancer awareness campaign, always in October, has long been the league’s most substantial plan to appeal to women”); see also Jamal Thalji, *Breast Cancer Awareness Month Is Promoted by the NFL in October, but Domestic Violence Awareness Month is Not*, TAMPA BAY TIMES (Oct. 10, 2014), <http://www.tampabay.com/news/business/after-domestic-violence-gaffes-is-nfl-the-best-ambassador-for-breast/2201581> [<http://perma.cc/SHB7-DHNM>] (“In October, the National Football League turns pink. Players wear pink gloves and pink cleats, honoring the pink ribbon that symbolizes Breast Cancer Awareness Month.”).

⁷ See BARRON H. LERNER, *THE BREAST CANCER WARS: HOPE, FEAR, AND THE PURSUIT OF A CURE IN TWENTIETH-CENTURY AMERICA* 17–29 (2001) (providing a thorough history of the treatment of breast cancer in the United States). Lerner describes the radical mastectomy as an operation which leaves “women with a deformed chest wall, hollow areas beneath the clavicle and the underarm, and, at times, persistent pain at the operative site and arm swelling known as lymphedema.” *Id.* at 32–33.

⁸ In the 1970s women physicians were in short supply. According to census data less than 10% of physicians were women. Today, a little more than 30% of physicians are women. For a discussion of the percentage of women in professional fields over time see Josh Mitchell, *Women Notch Progress*, WALL STREET J. (Dec. 4, 2012), <http://www.wsj.com/articles/SB10001424127887323717004578159433220839020> [<http://perma.cc/PX85-93M8>], noting that in 1970 women were 9.7% of doctors and in 2010 the percentage increased to 32.4%.

⁹ See LERNER, *supra* note 7, at 89.

¹⁰ See, e.g., Eloise C. Haun, *The Unconscious Breast*, 109 VA. MED. 750, 753 (1982) (“No matter how informed the patient is regarding treatment modalities for . . . ‘breast cancer’ and its metastases, the choice of treatment can be colored by effect. . . . If a

physicians believed that they were the best decision-makers for their women patients and their “functionless” body parts.¹¹

Scant attention was given to the fact that, for many women, the breast in and of itself is the essence of femininity symbolizing motherhood, womanhood, and sexuality.¹² Perhaps partly because the breast is so closely associated with femininity,¹³ women fear breast cancer and the loss of their breasts.¹⁴ Even when women chose a radical mastectomy fully appreciating and understanding available options, women still suffered both physical and psychological consequences.¹⁵ Women afflicted with breast cancer viewed themselves as victims of a brutal disease, and worse still, they viewed themselves as victims of paternalistic physicians.¹⁶ They often suffered from depression, anxiety, and fear in silence.¹⁷

Finally, during the 1970s, collective silence yielded to audible accounts of surviving breast cancer. For the first time, women began to speak publicly about their battle with breast cancer. These women showed incredible vulnerability by sharing their stories, and their act of bravery inspired legions

woman’s marriage partner or lover is strongly attached to the breast, research into medical literature will be focused on ways to preserve the breast so as to save the relationship.”); George E. Murphy, *The Clinical Management of Hysteria*, 247 JAMA 2559, 2559 (1982) (finding that hysteria is limited almost exclusively to women).

¹¹ See BARBARA EHRENREICH & DEIRDRE ENGLISH, COMPLAINTS AND DISORDERS: THE SEXUAL POLITICS OF SICKNESS 26–27 (1st ed. 1973) (noting that medical professionals viewed middle class women as frail and capable of only the lightest preoccupations).

¹² See Leslie Bennetts, *Relationships; Breast Cancer and Sexuality*, N.Y. TIMES (Mar. 1, 1982), <http://www.nytimes.com/1982/03/01/style/relationships-breast-cancer-and-sexuality.html> [<http://perma.cc/2DL2-TUEL>] (quoting Regina Kriss: “Your breasts are a symbol of your femininity, your desirability, your ability to entice. This is a very breast-oriented society, and it’s like everything you can offer a man is gone. It isn’t a vanity problem. It’s an essential part of your core existence as a woman.”).

¹³ See Lena Williams, *Women Who Lose Breasts Define Their Own Femininity*, N.Y. TIMES (Dec. 25, 1991), <http://www.nytimes.com/1991/12/25/health/women-who-lose-breasts-define-their-own-femininity.html> [<http://perma.cc/D8KH-2D5U>] (quoting Ann Marcou: “People used to hide in the closet. Individual women still tussle with their body because it’s so valued in society. Every woman who goes through this will wonder about her femininity and sexuality.”).

¹⁴ See Dina Roth Port, *Stopping Breast Cancer*, 65 PREVENTION 95, 95 (2013) (“Long before we get our first pimple, budding breasts remind us that we’re women in training. We love them, we hate them. We want them to grow bigger, we wish they’d stop growing No matter how conflicted we may be, breasts are part of our female identity, which may be why, for most of us, having breast cancer is our biggest fear.”).

¹⁵ See, e.g., Beth E. Meyerowitz, *Psychosocial Correlates of Breast Cancer and Its Treatments*, 87 PSYCHOL. BULL. 108, 112–13 (1980) (finding that the physical disruption of the radical mastectomy was substantial, making it difficult to sleep, have sexual intimacy, and adapt to clothing and body image problems; also finding that return to usual physical and social activities was also reportedly diminished in many women).

¹⁶ See Aurora P. Mamaril, *Preventing Complications After Radical Mastectomy*, 74 AM. J. NURSING 2000, 2003 (1974).

¹⁷ *Id.*

of women. Their stories increased public awareness and became the catalyst for improving care.¹⁸ Sharing stories began to foster a community and provided succor to women coping with breast cancer. Notably, Rose Kushner, a journalist, wrote about her quest to find a doctor willing to perform breast conserving surgery rather than the then standard radical mastectomy.¹⁹ Audre Lorde wrote a compelling account about her cancer diagnosis, its repercussions, her breast cancer journey, the search for alternative treatments, and her decision not to “pass” by wearing a prosthetic.²⁰ By publicizing their journey, women were no longer silent victims but instead evolved into vocal and proud survivors²¹ and “thrivers.”²²

Today public support and awareness of breast cancer is unparalleled.²³ The culture of silence has been replaced with at times the deafening roar of

¹⁸ When Betty Ford, then the first lady, in 1974 disclosed that she had undergone a mastectomy she opened the door for many women to speak publicly about breast cancer. See Natasha Singer, *Welcome, Fans, to the Pinking of America*, N.Y. TIMES (Oct. 15, 2011), http://www.nytimes.com/2011/10/16/business/in-the-breast-cancer-fight-the-pinking-of-america.html?_r=0 [<http://perma.cc/TW9Z-KCXQ>] (discussing that after Betty Ford went public about her breast cancer, the number of women having mammograms skyrocketed); see also *infra* pp. 855–56 (discussing informed consent legislation).

¹⁹ Kushner was a pioneering advocate for breast cancer patients. She argued for the need for individualized patient-centered decision-making with respect to breast cancer treatment. Kushner published three books on the topic. See ROSE KUSHNER, *BREAST CANCER: A PERSONAL HISTORY AND AN INVESTIGATIVE REPORT* 185–205 (1975); ROSE KUSHNER, *WHY ME?: WHAT EVERY WOMAN SHOULD KNOW ABOUT BREAST CANCER TO SAVE HER LIFE* 174–93 (First Signet Printing 1977) (1975); ROSE KUSHNER, *ALTERNATIVES: NEW DEVELOPMENTS IN THE WAR ON BREAST CANCER* 218–37 (First Warner Books 1985) (1984).

²⁰ See generally AUDRE LORDE, *THE CANCER JOURNALS* (1980).

²¹ Deena Metzger famously embraced surviving breast cancer by being photographed by Halla Hammid in a much-publicized photograph, “Tree.” In the photograph, Metzger is topless and fearlessly displaying her one-breasted torso with a tree tattoo covering the scar from her mastectomy. The photograph was accompanied by this statement by Metzger:

There is a fine red line across my chest where a knife entered, but now a branch winds about the scar and travels from arm to heart. . . . I have relinquished some of the scars. I have designed my chest with the care given to an illuminated manuscript. I am no longer ashamed to make love. . . . Love is a battle I can win. I have the body of a warrior who does not kill or wound. On the book of my body, I have permanently inscribed a tree.

DEENA METZGER, *TREE: ESSAYS & PIECES* 91 (1997); see also I Am No Longer Afraid Poster, Donnelly/Colt Catalog (Wingbow Press 1989), reprinted in LERNER, *supra* note 7, at 270. See generally BETTY ROLLIN, *FIRST, YOU CRY* (1976) (penning a poignant account of her bout with breast cancer).

²² Some breast cancer survivors prefer the term “thrivers.” For example, see generally BEVERLY VOTE, *HOW WE BECAME BREAST CANCER THRIVERS* (2010), for a collection of stories from women about how their faith helped them thrive in spite of their diagnosis.

²³ See Peggy Orenstein, *Our Feel-Good War on Breast Cancer*, N.Y. TIMES MAG. (Apr. 25, 2013), http://www.nytimes.com/2013/04/28/magazine/our-feel-good-war-on-breast-cancer.html?pagewanted=all&_r=0 [<http://perma.cc/FKP8-53TN>] (noting that Susan

advocates. Pink ribbons,²⁴ an international symbol of breast cancer, are commonly worn by both women and men throughout the year.²⁵ For the afflicted, the pink ribbon has become an emblem of courage in the face of a ruthless disease, and for family and friends of the afflicted, the pink ribbon is a tangible and steadfast image of solidarity.²⁶ In October, the official breast cancer awareness month, pink ribbons become ubiquitous. Although the U.S. has 175 officially designated “national health observances” ranging from National Radon Action Month to Food Allergy Month,²⁷ no other observance comes close to prominence of breast cancer awareness month.²⁸ In October, the messaging of breast cancer advocates seems to reach a frenetic pitch.²⁹ By

G. Komen is the largest breast-cancer organization and “[w]ith its dozens of races ‘for the cure’ and some 200 corporate partnerships, it may be the most successful charity ever at branding a disease; its relentless marketing has made the pink ribbon one of the most recognized logos of our time”).

²⁴ Evelyn Lauder, an executive at cosmetic behemoth Estee Lauder, worked with Alexandra Penney to create the pink ribbon campaign for breast cancer awareness. In the beginning, Mrs. Lauder and her husband paid for little bows to be given to women at department store makeup counters to remind them about breast exams. *See* Associated Press, *Lauder, Maker of Breast Cancer’s Pink Ribbon, Dies*, WALL STREET J. (Nov. 18, 2011), <http://www.wsj.com/articles/SB10001424052970204224604577035092160570480> [<http://perma.cc/7RF7-C8FQ>].

²⁵ *See, e.g.*, Terri Lynne Helge, *The Taxation of Cause-Related Marketing*, 85 CHI.-KENT L. REV. 883, 915 (2010) (noting that a pink ribbon is the commonly worn universal symbol for breast cancer awareness).

²⁶ Some states have even designated a special time each year to celebrate women who have been diagnosed by wearing pink. *See, e.g.*, LA. STAT. ANN. § 1:58.5(B) (Supp. 2015) (providing that “[i]n honor of those who have been diagnosed with breast cancer, October twenty-fifth, twenty-sixth, and twenty-seventh are hereby designated annually as ‘Care Enough to Wear Pink’ days through the state of Louisiana”); *see also* N.J. STAT. ANN. § 36:2-86 (West Supp. 2015) (designating the month of October as “Breast Cancer Awareness Month” in the state of New Jersey).

²⁷ *See 2015 National Health Observances*, HEALTHFINDER.GOV, <http://healthfinder.gov/NHO/nho.aspx?year=2015> [<http://perma.cc/2L8B-8G8V>].

²⁸ October is also Home Eye Safety Month, National Down Syndrome Awareness Month, and Sudden Infant Death Syndrome (SIDS) Awareness Month, but there are no marketing tie-ins with these causes. *See id.* In contrast, the marketing tie-ins with breast cancer are substantial. *See, e.g.*, Tara Parker-Pope, *How to Tell if a Pink-Ribbon Product Really Helps Breast-Cancer Efforts*, WALL STREET J. (Oct. 10, 2006), <http://www.wsj.com/articles/SB116043734736287479> [<http://perma.cc/2C54-Z6U8>] (“Store shelves are filling up with pink products tied to October’s Breast Cancer Awareness month There is a seemingly endless variety of pink products on offer these days. The options range from . . . pink M&Ms and Tic Tacs . . . to home appliances such as a pink KitchenAid mixer or pink Dyson vacuum cleaner.”).

²⁹ *See, e.g.*, Jean Hopfensperger, *Pink Blitz for Breast Cancer Stirs Debate*, STARTRIB. (Oct. 17, 2011), <http://www.startribune.com/pink-blitz-for-breast-cancer-stirs-debate/131926483/> [<http://perma.cc/DF3W-MK9U>] (noting that in October “options are everywhere. Sit down at a restaurant and get offered a ‘pink drink.’ Head to the coffee shop and get handed a cup wrapped in a pink band. Click on the TV and check out NFL players in pink shoes and arm bands. Visit a high school baseball game and find a fan wearing the

linking brands and products to breast cancer awareness, breast cancer charities have been able to ramp up awareness and inundate shelves with pink.³⁰ Their strategy has been so successful in marketing that “pink” is now a verb.³¹

Breast cancer advocates have successfully harnessed personal stories,³² organization,³³ and money³⁴ to promote awareness. Promotion activities have reached the judiciary spawning case law on First Amendment rights.³⁵ In addition, advocates have taken their message to both state and federal legislators. For example, advocates were instrumental in the passage of

T-shirt ‘Don’t Let Cancer Steal Second Base.’”); *see also* Singer, *supra* note 18 (“The entire Cowboys stadium [is pink]. Pink is everywhere: around the goalposts, in the crowd, on the players’ cleats, towels and wristbands.”).

³⁰ *See* Amy McFadden, *Think Pink and Buy Pink for Breast Cancer Research*, ST. J. REG. (Oct. 12, 2008), <http://www.sj-r.com/article/20081012/NEWS/310129961/0/SEARCH> [<http://perma.cc/EC49-T3ST>] (“Beyond the ubiquitous pink ties connected to the ‘Real Men Wear Pink’ campaign, and pink lingerie and sleepwear for women, items range from T-shirts to socks, to pots and pans, to ink pens and office supplies, to household appliances.”).

³¹ *See* Singer, *supra* note 18 (“In marketing circles, ‘to pink’ means to link a brand or a product or even the entire National Football League to one of the most successful charity campaigns of all time.”).

³² For example, Senator Tom Harkin touts his support for government-funded preventative care like mammograms as stemming from personal experience. *See* Jane C. Timm, *Emotional Tom Harkin Shares how Preventive Women’s Health Services Could Have Saved His Sisters’ Lives*, MSNBC (Aug. 1, 2012), <http://www.msnbc.com/msnbc/emotional-tom-harkin-shares-how-preventi> [<http://perma.cc/S7ZE-QD22>] (quoting Senator Harkin describing his sisters’ experience with breast cancer: “They didn’t have any money. They didn’t really have health care coverage. When my older sister Marianne died and we went to her funeral, her younger sister Silvia was there and had no idea that she also had breast cancer. Within two years, she was dead also. And they left young families.”).

³³ *See* Michelle M. Mello & Troyen A. Brennan, *The Controversy over High-Dose Chemotherapy with Autologous Bone Marrow Transplant for Breast Cancer*, 20 HEALTH AFF. 101, 106 (2001) (“[T]he degree of political organization and mobilization among breast cancer patients and their advocates is high. Approximately 400 support . . . groups are organized under the aegis of the National Alliance of Breast Cancer Organizations (NABCO), which engages in large-scale educational and lobbying activities.”).

³⁴ *See, e.g.,* Michele Munz, *After Support Drops for Komen, New Director Visits St. Louis to Bring Focus to Mission*, ST. LOUIS POST-DISPATCH (Nov. 7, 2013), http://www.stltoday.com/lifestyles/health-med-fit/health/after-support-drops-for-komen-new-director-visits-st-louis/article_4661ef89-1b40-57bf-b32e-fb511935af58.html [<http://perma.cc/ADS8-JMHD>] (noting that Susan G. Komen, the largest charity devoted to breast cancer, has invested “more than \$800 million in breast cancer research and \$1.6 billion in screening, education and treatment programs in more than 30 countries since its inception”).

³⁵ Students have challenged bans implemented by school districts which prohibit wearing “I heart boobies!” bracelets as part of a nationally recognized breast cancer awareness campaign. *See, e.g.,* B.H. *ex rel.* Hawk v. Easton Area Sch. Dist., 725 F.3d 293, 301 (3d Cir. 2013) (en banc); J.A. v. Fort Wayne Cmty. Schs., No. 1:12-CV-155 JVB, 2013 WL 4479229, at *6 (N.D. Ind. Aug. 20, 2013).

mammography standards.³⁶ Advocates also successfully lobbied for legislation mandating that insurers provide coverage for breast reconstruction following mastectomies³⁷ and also fought for quicker access to drugs.³⁸

During the 1980s, breast cancer survivors advocated for breast cancer informed consent laws in state legislatures across the country.³⁹ These women believed that they had a fundamental right to be made aware of treatment alternatives and to be given choices.⁴⁰ They shared their stories of consenting to a biopsy only to wake up to find that they had received a radical mastectomy.⁴¹ Advocates argued that even though studies consistently showed that less invasive surgery (lumpectomy with radiation, known as breast-conserving surgery, or “BCS”) yielded outcomes equivalent to those of the radical mastectomy and that the use of radical mastectomies remained alarmingly high.⁴²

Based on their lobbying efforts, twenty-two states passed breast cancer informed consent laws.⁴³ The informed consent laws yielded tepid results.

³⁶ See Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b (2012); see also Florence Houn et al., *The Mammography Quality Standards Act of 1992: History and Process*, 50 FOOD & DRUG L.J. 485, 487 (1995) (“In response to growing public awareness and concern about the devastating effects of breast cancer, Congress passed MQSA on October 27, 1992 to ensure national quality standards for mammography services.”).

³⁷ Congress passed the Women’s Health and Cancer Rights Act of 1998 in response to public pressure from breast cancer advocates. See 29 U.S.C. § 1185b (2012) (mandating that if a group health plan provides coverage for a mastectomy then it shall also provide benefits for breast reconstruction).

³⁸ When insurers denied payment for expensive high-dose chemotherapy-autologous bone marrow transplants, which was used to treat women with advanced breast cancer, breast cancer survivors advocated state legislators and some states passed laws mandating coverage. Although the laws were repealed when controlled studies showed that the treatment was not effective. See e.g., N.H. REV. STAT. ANN. § 415:18-c (2006) (repealed 2010); VA. CODE ANN. § 38.2-3418.1:1 (2007) (repealed 2008).

³⁹ See Theresa Montini, *Resist and Redirect: Physicians Respond to Breast Cancer Informed Consent Legislation*, 26 WOMEN & HEALTH 85, 86 (1997).

⁴⁰ *Id.* at 91.

⁴¹ *Id.*

⁴² See Nancy N. Baxter et al., *Trends in the Treatment of Ductal Carcinoma In Situ of the Breast*, 96 J. NAT’L CANCER INST. 443, 443 (2004) (finding that “many patients were found to undergo aggressive surgical therapy, including mastectomy and axillary dissection”); Ann B. Nattinger et al., *Minimal Increase in Use of Breast-Conserving Surgery from 1986 to 1990*, 34 MED. CARE 479, 479 (1996) (“Despite the substantial evidence supporting BCS as an alternative to mastectomy, the overall use of BCS in Medicare inpatients increased minimally from 1986 to 1990.”).

⁴³ See CAL. HEALTH & SAFETY CODE § 109277 (West 2012); FLA. STAT. ANN. §§ 458.324, 459.0125 (West 2007); GA. CODE ANN. § 43-34-21 (2011); HAW. REV. STAT. ANN. § 671-3 (West Supp. 2014); 20 ILL. COMP. STAT. ANN. 2310/2310-345 (West 2015); KAN. STAT. ANN. § 65-2836(m) (West 2002); KY. REV. STAT. ANN. § 311.935 (LexisNexis 2011); LA. STAT. ANN. §§ 40:1300.151–.154 (2008); ME. REV. STAT. ANN. tit. 24, § 2905-A (2015); MD. CODE ANN., HEALTH–GEN. § 20-113 (LexisNexis 2009); MD. CODE ANN.,

Researchers found that the state laws mandating the disclosure of alternatives for the treatment of breast cancer were temporarily associated with a slight increase in the use of breast-conserving surgery.⁴⁴ The increases were short lived, however, ranging from three to twelve months after which the use of breast-conserving surgery reverted to previous levels.⁴⁵

Most recently, breast cancer advocates have lobbied for dense breast tissue notification legislation. Dense breast tissue notification legislation was pioneered by Nancy Cappello of Woodbury, Connecticut.⁴⁶ Mrs. Cappello had regular mammograms for over ten years before her doctor found a suspicious ridge during a manual exam.⁴⁷ When her doctor found the ridge, Cappello was immediately referred for a mammogram and ultrasound on the same day.⁴⁸ The mammogram once again failed to detect the tumor, but the ultrasound found a tumor the size of a quarter. When Cappello inquired as to why the mammogram was unable to detect her tumor, her doctor for the first time mentioned that she had dense breasts, which can hinder the ability of a radiologist to detect cancer on mammographic film.⁴⁹ After undergoing a mastectomy, chemotherapy, radiation and hormone treatment, Capello began to advocate for legislation requiring radiologists or mammographic facilities to inform women when they have dense breasts.⁵⁰

Cappello was outraged at the thought of women having yearly mammograms without knowing that their dense breast tissue could obscure

HEALTH OCC. § 14-404 (LexisNexis 2014); MASS. ANN. LAWS ch. 111, § 70E (LexisNexis 2013); MICH. COMP. LAWS ANN. §§ 333.17013–.17513 (West 2008); MINN. STAT. ANN. § 144.651(9) (West Supp. 2015); MO. ANN. STAT. § 376.1250 (West 2013); MONT. CODE ANN. § 37-3-333 (2014); N.J. STAT. ANN. § 26:2-168 (West 2007); *id.* § 45:9-22.3a, 3b (West 2004); N.Y. PUB. HEALTH LAW §§ 2404–2409 (McKinney 2012 & Supp. 2015); 35 PA. STAT. AND CONS. STAT. ANN. §§ 5641–5642 (West 2012); TEX. HEALTH & SAFETY CODE ANN. §§ 86.001–.005, .011, .012 (West 2010) (repealed 2013); VA. CODE ANN. § 54.1-2971 (2005) (repealed 2008); W. VA. CODE ANN. §§ 16-33-1 to -12 (LexisNexis 2011).

⁴⁴ See Ann Butler Nattinger, *The Effect of Legislative Requirements on the Use of Breast-Conserving Surgery*, 335 NEW ENG. J. MED. 1035, 1039 (1996) (finding that states with directive disclosure laws saw an increase in breast conserving surgery ranging from 6–13%).

⁴⁵ *Id.*

⁴⁶ See Denise Grady, *New Laws Add a Divisive Component to Breast Screening*, N.Y. TIMES (Oct. 24, 2012), http://www.nytimes.com/2012/10/25/health/laws-tell-mammogram-clinics-to-address-breast-density.html?_r=0 [<http://perma.cc/6Y66-XNUZ>].

⁴⁷ *Id.*

⁴⁸ See Melinda Beck, *The Latest Mammogram Controversy: Density*, WALL ST. J. (Aug. 6, 2012), <http://www.wsj.com/articles/SB10000872396390444246904577573181463638846> [<http://perma.cc/FYR7-3NHG>].

⁴⁹ *Id.*

⁵⁰ Capello is the founder of Are You Dense Advocacy Inc., which advocates for legislative and regulatory efforts to standardize the communication of dense breast tissue to women. See *About Us*, ARE YOU DENSE? ADVOCACY, <http://areyoudenseadvocacy.org/about/> [<http://perma.cc/P3LF-HU2Q>] [hereinafter ARE YOU DENSE?].

cancerous tumors.⁵¹ Thus, she tirelessly lobbied Connecticut legislators and in 2009, Connecticut became the first state to mandate standardized communication of dense breast tissue in mammography reports given to patients.⁵² The required notification states:

If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, which can include a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician's office and you should contact your physician if you have any questions or concerns about this report.⁵³

In addition, Connecticut also mandates that insurers cover the cost of expensive ultrasound scans for women who have dense breast tissue.⁵⁴ Cappello was buoyed by her success with Connecticut legislators and launched a national advocacy organization, "Are You Dense Advocacy."⁵⁵ The stated goal of her organization is to "[a]dvocate for and support state and federal legislative and regulatory efforts to standardize the communication of dense breast tissue to women."⁵⁶ Cappello's success in Connecticut has inspired women across the country to advocate for similar legislation in their states.

Texas became the second state to enact density notification legislation. Texas legislators passed a notification bill, also known as Henda's law, in 2011.⁵⁷ Henda Salmeron, like Cappello, had regular mammograms which failed to detect cancer.⁵⁸ Salmeron detected a lump in her breast and went back for another mammogram which again failed to detect the tumor.⁵⁹ However, this time she was referred for an ultrasound which did detect the tumor.⁶⁰

⁵¹ See Grady, *supra* note 46.

⁵² *Id.*

⁵³ CONN. GEN. STAT. ANN. § 38a-503(c) (West 2012).

⁵⁴ See *id.* § 38a-503(a)(2). Connecticut is one of only two states that mandates notification of breast density and mandates that insurers cover supplemental screenings.

⁵⁵ See David Katz, *Being Less Dense About Breast Cancer Screenings*, HUFFINGTON POST (Sept. 13, 2013), http://www.huffingtonpost.com/david-katz-md/breast-cancer-screening_b_3922681.html [<http://perma.cc/LS73-2L4H>] (noting that Are You Dense Advocacy began in 2011 as a result of a "flurry of interest" in breast density legislation).

⁵⁶ See ARE YOU DENSE?, *supra* note 50.

⁵⁷ See TEX. HEALTH & SAFETY CODE ANN. § 86.013(a) (West Supp. 2014).

⁵⁸ Bradford Pearson, *Henda's Law*, D MAG. (Nov. 2011), <http://www.dmagazine.com/publications/d-magazine/2011/november/how-hendas-law-was-born> [<http://perma.cc/4UFZ-GGEA>] (reporting that after Salmeron lost the weight, she noticed a lump, about the size of a pea near her right breastbone: "Mammograms at age 35, 40, 41, and 42 were normal, but Salmeron couldn't let it go.").

⁵⁹ *Id.*

⁶⁰ *Id.*

Salmeron was diagnosed with an advanced form of breast cancer.⁶¹ While undergoing radiation treatments, Salmeron began advocating for dense breast tissue notification legislation in Texas.⁶² Salmeron worked with legislators to draft a bill, and her efforts came to fruition when Henda's law was passed in 2011.⁶³

In 2012, three more states California,⁶⁴ Virginia,⁶⁵ and New York⁶⁶ passed similar density notification statutes. California's bill was inspired by Amy Colton, a nurse whose breast cancer went undetected despite years of regular screening mammograms.⁶⁷ Similarly, Cathryn Tatusko, a nurse who was diagnosed with late-stage breast cancer after fourteen years of "normal" mammograms, tirelessly lobbied legislators in Virginia.⁶⁸ New York's statute was passed thanks in part to the lobbying efforts of another dense woman, JoAnn Pushkin. Like the others, Pushkin was diagnosed with advanced cancer despite having had regular mammograms.⁶⁹

Their stories are powerful. The density notification advocates present compelling narratives to legislators. Each took ownership of their health by living healthy and active lifestyles. Each believed that having regular mammograms would ensure early detection of breast cancer. Yet, each was betrayed by their faith in mammograms, which allowed them to go years without realizing that cancer was growing in their breasts. United by anger, they have lobbied legislators to mandate that dense women be informed that cancer may be obscured on mammography film.

Their message is hard to resist. They are advocating to inform and empower women. They want to standardize, improve, and promote increased doctor-patient communication. Their message is so enticing that state legislators across the country are listening. Inspired by their indignation and a

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ CAL. HEALTH & SAFETY CODE § 123222.3(a) (West Supp. 2015).

⁶⁵ VA. CODE ANN. § 32.1-229 (2011).

⁶⁶ N.Y. PUB. HEALTH LAW § 2404-c (McKinney Supp. 2015).

⁶⁷ See Steven Harmon, *Is It a Woman's Right to Know She Has a Condition That Could Mask Breast Cancer?*, SAN JOSE MERCURY NEWS (Sept. 6, 2011), http://www.mercurynews.com/ci_18837571 [<http://perma.cc/QQ5B-MN2S>] (reporting that Colton religiously had a mammogram every year since turning forty).

⁶⁸ See Laura Vozzella, *Breast-Density Bill to Become Law in Virginia*, WASH. POST (Feb. 13, 2012), http://www.washingtonpost.com/local/dc-politics/virginia-to-require-radiologists-to-notify-mammogram-patients-of-breast-density/2012/02/09/gIQArDFpBR_story.html [<http://perma.cc/W9NY-E8HD>] (reporting that Tatusko had mammograms for fourteen straight years that showed no signs of cancer).

⁶⁹ See Liz Szabo, *Study: Dense Breast Tissue Doesn't Add Cancer Death Risk*, USA TODAY (Aug. 21, 2012), <http://usatoday30.usatoday.com/news/health/story/2012-08-20/breast-density-death/57171282/1> [<http://perma.cc/FG9Z-VZX5>] (noting that Pushkin's annual mammogram missed her breast cancer).

sense of duty to women, lawmakers have taken action. In 2013, Alabama,⁷⁰ Hawaii,⁷¹ Maryland,⁷² Nevada,⁷³ North Carolina,⁷⁴ Oregon,⁷⁵ Pennsylvania,⁷⁶ and Tennessee⁷⁷ enacted density notification laws. Arizona,⁷⁸ Massachusetts,⁷⁹ Minnesota,⁸⁰ Missouri,⁸¹ New Jersey,⁸² Ohio,⁸³ and Rhode Island⁸⁴ passed density notification statutes in 2014. In 2015, Delaware,⁸⁵ Michigan,⁸⁶ and North Dakota⁸⁷ have enacted density notification laws. Currently, twenty-three states have enacted dense breast tissue notification laws. Many states currently have bills pending in their legislatures⁸⁸ and a federal bill has been introduced in the House⁸⁹ and Senate.⁹⁰

While the stories of Cappello and others whose cancer was obscured by dense breast tissue are compelling, personal narratives are not necessarily the best basis for driving public policy. Such stories are anecdotes and provide little in the way of determining the magnitude, scope, and source of the problem. Such narratives always militate in favor of action, without fully appreciating the downside consequences. From a legislative prospective, there is no need to rigorously examine the evidence because delaying action risks the lives of unsuspecting dense women. This is especially true when the requested action seems relatively easy to implement.

This Article presents the first critical analysis of the various types of density notification statutes. Part II provides context by providing background about breast cancer and how it is diagnosed. Part III explores the ideal of patient autonomy and analyzes whether dense breast tissue notification statutes empower or undermine women. Part IV examines how these statutes effect

⁷⁰ ALA. CODE § 22-13-71(a) (LexisNexis Supp. 2014).

⁷¹ HAW. REV. STAT. ANN. § 321-46(a) (West Supp. 2014).

⁷² MD. CODE ANN., HEALTH-GEN. § 20-115(c)(2) (LexisNexis Supp. 2014).

⁷³ NEV. REV. STAT. ANN. § 457.1857(4) (LexisNexis Supp. 2013).

⁷⁴ N.C. GEN. STAT. § 130A-215.5(a) (2013).

⁷⁵ OR. REV. STAT. § 431.823 (2013).

⁷⁶ 35 PA. STAT. AND CONS. STAT. ANN. § 10229.2(b) (West Supp. 2015).

⁷⁷ TENN. CODE ANN. § 63-6-245(b) (Supp. 2014).

⁷⁸ ARIZ. REV. STAT. ANN. § 36-415(A) (Supp. 2014).

⁷⁹ MASS. ANN. LAWS ch. 111 § 5Q(b) (LexisNexis Supp. 2013).

⁸⁰ MINN. STAT. ANN. § 144.1212(2) (West Supp. 2015).

⁸¹ MO. ANN. STAT. § 192.769(1) (West Supp. 2015).

⁸² N.J. STAT. ANN. § 26:2-184.3 (West Supp. 2015).

⁸³ OHIO REV. CODE ANN. § 3702.40(B) (West Supp. 2015).

⁸⁴ 23 R.I. GEN. LAWS § 23-12.9-2 (Supp. 2014).

⁸⁵ DEL. CODE ANN. tit. 16, § 3201A (West, Westlaw through 80 Laws 2015, ch. 193).

⁸⁶ MICH. COMP. LAWS ANN. § 333.13524(1) (West Supp. 2015).

⁸⁷ N.D. CENT. CODE § 23-01-43 (Supp. 2015).

⁸⁸ See, e.g., H.F. 171, 86th Gen. Assemb., 1st Reg. Sess. (Iowa 2015); S.B. 5040, 64th Leg., Reg. Sess. (Wash. 2015).

⁸⁹ Breast Density and Mammography Reporting Act of 2015, H.R. 716, 114th Cong. (2015).

⁹⁰ Breast Density and Mammography Reporting Act of 2015, S. 370, 114th Cong. (2015).

patient care and calls into question the wisdom of having legislators dictating the standard of care and the content of physician-patient communications. Part V offers a path forward by calling on states and the federal government to inform women broadly through public health initiatives instead of mandating standardized density notification disclosures. In addition, Part V also offers suggestions for legislators who, nonetheless, wish to implement mandatory dense breast tissue notification legislation. Finally, Part VI offers a brief conclusion.

II. THE ANATOMY OF BREAST CANCER

Breast cancer advocates have successfully promoted awareness since the 1970s. As Judge Tinder has eloquently stated, “[h]ardly a person among us has not been touched either directly or indirectly by the occurrence of this virulent disease in themselves, a family member, friend, or loved one.”⁹¹ Consequently, most women are acutely aware of the statistics. One in eight women will develop breast cancer at some point in her life.⁹² The risk of developing breast cancer increases with age.⁹³ Each year, over 200,000 women are diagnosed with breast cancer and over 40,000 women die of breast cancer.⁹⁴ However, when breast cancer is detected early and confined to the breast, the five-year survival rate is 98%.⁹⁵ Women who are diagnosed with stage I or stage II breast cancer have well over a 90% five-year relative survival rate.⁹⁶ In contrast, women diagnosed with stage IV breast cancer have a 22% five-year relative survival rate.⁹⁷ The message behind the statistics is both sobering and empowering. Breast cancer, the opponent, is deadly, but women can successfully win the war if the cancer is detected early. Thus, early detection has been the key mantra for breast cancer advocates. Women are

⁹¹ *Harris v. Mut. of Omaha Cos.*, IP 92-1089-C, 1992 WL 421489, at *1 (S.D. Ind. Aug. 26, 1992).

⁹² AM. CANCER SOC’Y, BREAST CANCER 8 (2014), <http://www.cancer.org/acs/groups/cid/documents/webcontent/003090-pdf.pdf> [<http://perma.cc/94W7-KEQV>] [hereinafter ACS, BREAST CANCER].

⁹³ Age, sex, personal history of cancer, BRCA1 and BRCA2 inherited genetic mutations, radiation exposure during youth, and family history of breast cancer are among the factors that have the greatest impact on breast cancer risk. See *Risk Factors Summary Table of Relative Risks*, SUSAN G. KOMEN, <http://ww5.komen.org/BreastCancer/RiskFactorsSummaryTable.html> [<http://perma.cc/D7Z9-JZTJ>] (last updated Apr. 18, 2013). In contrast, the major risk factors for heart disease are smoking, physical inactivity, obesity, and high blood pressure and cholesterol, which are largely controllable. See *Know Your Risk Factors*, WOMEN HEART, http://www.womenheart.org/?page=Support_KnowRisk [<http://perma.cc/XEE2-75FS>].

⁹⁴ See ACS, BREAST CANCER, *supra* note 92, at 8–9.

⁹⁵ See SUSAN G. KOMEN FOR THE CURE, FACTS FOR LIFE: BREAST CANCER FACTS 1 (2009), <http://www.komenscmm.org/assets/education-materials/breast-cancer-facts.pdf> [<http://perma.cc/P29P-URWQ>].

⁹⁶ See ACS, BREAST CANCER, *supra* note 92, at 48.

⁹⁷ *Id.*

encouraged to have regular mammograms.⁹⁸ This encouragement is often coupled with the familiar rhetoric that “mammograms are the best weapon against breast cancer.”⁹⁹

A mammogram is a low-dose X-ray procedure that captures images of the breast that are used to evaluate breast tissue.¹⁰⁰ A technician places the breast on a clear plastic plate and another plate firmly presses the breast from above.¹⁰¹ Together the plates flatten the breast, holding it still while the X-ray is taken.¹⁰² Typically, two X-ray pictures are taken of each breast and the pictures are sent to a radiologist for review.¹⁰³ Mammography facilities are required to provide a written report of the results of the mammogram to both the patient and the health care provider who ordered the screening in writing within thirty days.¹⁰⁴ Additionally, if the results are “Suspicious” or “Highly suggestive of malignancy,” the facility is required to make reasonable attempts to communicate the results to both the patient and the patient’s referring physician as soon as possible.¹⁰⁵

Mammography prevalence has increased from 29% in 1987 to 67% in 2010.¹⁰⁶ More than thirty-eight million mammograms are performed each year in the United States at over 8,000 facilities.¹⁰⁷ In 1992, Congress passed the Mammography Quality Standards Act (MQSA). The MQSA ensures that radiology facilities offering mammography meet minimum quality

⁹⁸ See *Guidelines for Early Detection of Breast Cancer*, AM. CANCER SOC’Y, <http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer> [<http://perma.cc/DVG6-SQX4>] (last revised Oct. 20, 2015) (recommending a yearly mammogram for women beginning at age 40 and a clinical breast exam for women every three years for women in their 20s and 30s).

⁹⁹ See, e.g., Mary Duenwald, *Putting Cancer Screening to the Test*, N.Y. TIMES (Oct. 15, 2002), <http://www.nytimes.com/2002/10/15/health/putting-cancer-screening-to-the-test.html> [<http://perma.cc/2ND9-7BPD>] (quoting Lillie Shockney breast cancer survivor and registered nurse: “Mammography is still at this moment in time our best weapon for early detection. I cannot imagine a woman not pursuing it.”).

¹⁰⁰ AM. CANCER SOC’Y, MAMMOGRAMS AND OTHER BREAST IMAGING TESTS 1, 7 (2014), <http://www.cancer.org/acs/groups/cid/documents/webcontent/003178-pdf.pdf> [<http://perma.cc/Q35E-SQD3>] [hereinafter ACS, MAMMOGRAMS].

¹⁰¹ *Id.*

¹⁰² *What Is a Mammogram and When Should I Get One?*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/cancer/breast/basic_info/mammograms.htm [<http://perma.cc/JR7L-72TJ>] (last updated Oct. 31, 2013).

¹⁰³ ACS, MAMMOGRAMS, *supra* note 100, at 3–4.

¹⁰⁴ 21 C.F.R. § 900.12(c)(2), (3)(i) (2011).

¹⁰⁵ *Id.* § 900.12(c)(2), (3)(ii).

¹⁰⁶ See AM. CANCER SOC’Y, BREAST CANCER FACTS & FIGURES 2013–2014, at 20 (2013), <http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-042725.pdf> [<http://perma.cc/T6TD-SHTF>].

¹⁰⁷ See *Radiation-Emitting Products: 2015 Scorecard Statistics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/DocumentArchives/ucm432658.htm> [<http://perma.cc/6Z9U-A6XV>] (last updated Oct. 1, 2015).

standards.¹⁰⁸ Mammograms cost on average between \$50 and \$200,¹⁰⁹ and annual spending on mammograms reaches nearly eight billion dollars in the U.S.¹¹⁰ Yet, despite its widespread use, mammography has its drawbacks. For dense women like Cappello, the most serious drawback is that mammography is not as effective at detecting cancer when the breast tissue is dense.

Breasts are made up of glandular (milk ducts), fat (adipose), and supportive tissue with a system of lymph nodes running through the center.¹¹¹ Breast density refers to the amount of fatty and fibro-glandular tissue seen in the breast as viewed on mammography film.¹¹² Breasts are considered dense when there is more glandular tissue than fatty and supportive tissue.¹¹³ On mammography images, dense breast tissue looks white, just like cancer.¹¹⁴ Thus, dense breast tissue can obscure cancerous tumors. For dense women, the sensitivity of film mammography is between 62% and 68%.¹¹⁵ In comparison, the sensitivity of film mammography is greater than 85% for women with fatty breasts. The main goal of any cancer-screening test is to correctly identify those individuals who have cancer.¹¹⁶ How well a screening test correctly identifies with the disease is referred to as sensitivity.¹¹⁷ When sensitivity is high, very few cases are missed. Thus, for dense women, mammography is significantly less sensitive, which means that their breast cancer is less likely to be visible on mammographic film.

¹⁰⁸ The FDA is the agency charged with certifying mammography facilities. See Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b (2012).

¹⁰⁹ See Melinda Beck, *New Screening Tests for Hard-to-Spot Breast Cancers*, WALL STREET J. (Feb. 23, 2015), <http://www.wsj.com/articles/new-screening-tests-for-hard-to-spot-breast-cancers-1424731497> [<http://perma.cc/WX36-5UNR>] (discussing the cost of various screenings). Because screening mammograms are deemed a preventative service, it is typically covered without copayments or deductibles for women with private insurance. In addition, Medicaid and Medicare both cover the cost of the mammogram screenings. See ACS, MAMMOGRAMS, *supra* note 100, at 6.

¹¹⁰ See Denise Grady, *3-D Mammography Test Appears to Improve Breast Cancer Detection Rate*, N.Y. TIMES (June 24, 2014), http://www.nytimes.com/2014/06/25/health/breast-cancer-3d-mammography-test-x-ray.html?_r=0 [<http://perma.cc/W298-AZ94>].

¹¹¹ See VALERIE F. ANDOLINA & SHELLY L. LILLÉ, MAMMOGRAPHIC IMAGING 71 (3d ed. 2010).

¹¹² See AM. CONG. OF OBSTETRICIANS & GYNECOLOGISTS, N.J. SECTION, DISCUSSING BREAST DENSITY 3, <https://www.acog.org/-/media/Sections/NJ/DiscussingBreastDensity.pdf> [<http://perma.cc/3XR4-6LYN>] [hereinafter DISCUSSING BREAST DENSITY].

¹¹³ See MIRIAM E. NELSON & JENNIFER ACKERMAN, THE STRONG WOMEN'S GUIDE TO TOTAL HEALTH 251 (2010).

¹¹⁴ See Grady, *supra* note 46 (“On mammograms, dense breasts look white, and so does cancer, so the tissue can hide tumors. Fatty breasts show up mostly black, so tumors stand out.”).

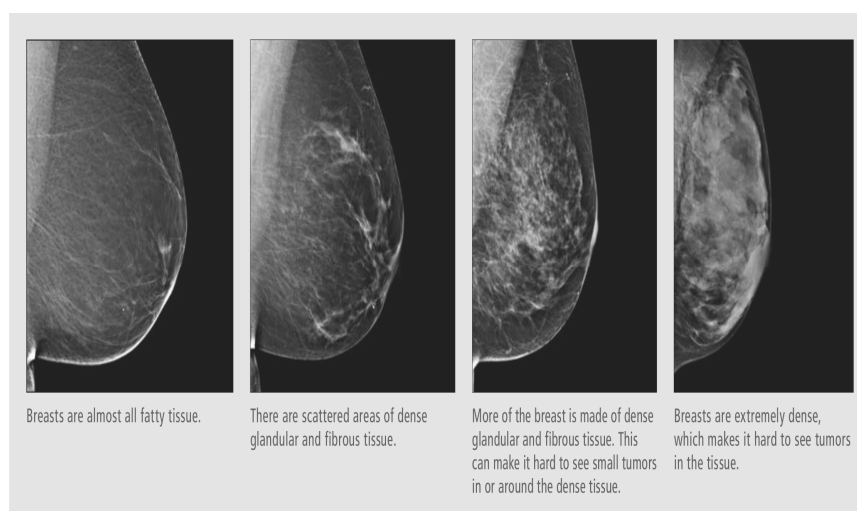
¹¹⁵ See Priscilla J. Slanetz et al., *Breast-Density Legislation—Practical Considerations*, 372 NEW ENG. J. MED. 593, 593 (2015).

¹¹⁶ *Id.*

¹¹⁷ See BRANI VIDAKOVIC, STATISTICS FOR BIOENGINEERING SCIENCES 111 (2011) (explaining the difference between test sensitivity and specificity).

Breast density is typically visually determined by the radiologist who reads the mammogram.¹¹⁸ The American College of Radiology defines breast density using four categories: (1) the breasts are almost entirely fatty; (2) there are scattered areas of fibro-glandular density; (3) the breasts are heterogeneously dense; and (4) the breasts are extremely dense.¹¹⁹ 10% of women have almost entirely fatty (non-dense) breasts and 10% of women have extremely dense breasts.¹²⁰ Thus, the vast majority of women have some degree of dense breast tissue.

Figure 1: *Breast Density Categories from fatty, non-dense (left side) to extremely dense (right side)*¹²¹



Specifically, most women have breasts with a combination of glandular and fibrous tissue.¹²² Forty percent of women have scattered areas of fibro-

¹¹⁸ See Dana S. Al Mousa et al., *How Mammographic Breast Density Affects Radiologists' Visual Search Patterns*, 21 ACAD. RADIOLOGY 1386, 1386 (2014) (explaining how breast density affects visual perceptions of radiologists interpreting mammograms).

¹¹⁹ AM. COLL. OF RADIOLOGY, ACR BI-RADS ATLAS—MAMMOGRAPHY 124 (5th ed. 2013), <http://www.acr.org/~media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/01%20Mammography/02%20%20BIRADS%20Mammography%20Reporting.pdf> [<http://perma.cc/WN3N-GJTZ>].

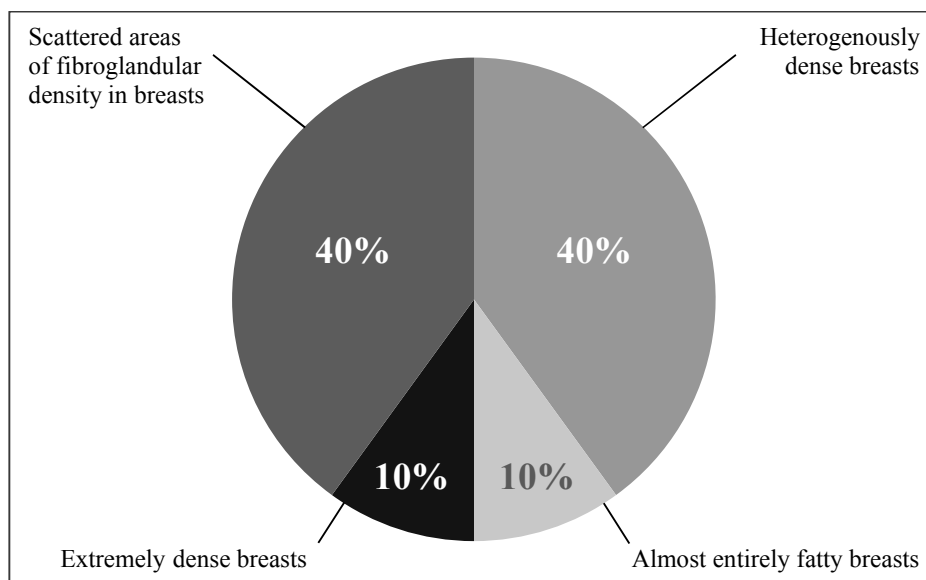
¹²⁰ See DISCUSSING BREAST DENSITY, *supra* note 112, at 3.

¹²¹ AM. CANCER SOC'Y, BREAST DENSITY AND YOUR MAMMOGRAM REPORT 1 (July 2015), <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-039989.pdf> [<http://perma.cc/9D2G-5QBC>] (Copyright © 2015 American Cancer Society. All rights reserved.).

¹²² *Shedding Light on Breast Density*, AM. COLL. OF RADIOLOGY (Oct. 5, 2012), <http://www.acr.org/News-Publications/News/News-Articles/2012/ACR-Bulletin/201210-Shedding-Light-on-Breast-Density> [<http://perma.cc/TMB7-AKC4>].

glandular tissue, and 40% of women have heterogeneously dense breast tissue.¹²³ The 50% of women who have either heterogeneously dense or extremely dense breasts are considered clinically dense.¹²⁴ However, breast density is not static. Dense breast tissue tends to decrease with age.¹²⁵

Figure 2: *Breast Density Among Total U.S. Adult Female Population*¹²⁶



As the figure illustrates, a large percentage of women have dense breast tissue. While scores of middle-aged women are told to have annual screening mammograms without any qualifications,¹²⁷ few dense women are ever told about their breast density until they are diagnosed with advanced breast cancer. There is no disclaimer that warns dense women that a mammogram might not detect their cancer. For density advocates like Cappello, who had years of annual mammograms with undetected cancer lurking and growing inside of their dense breast tissue, women simply need to be told when they

¹²³ See DISCUSSING BREAST DENSITY, *supra* note 112, at 3.

¹²⁴ *Id.*

¹²⁵ *Louisville's First 3D Mammography—Digital Breast Tomosynthesis*, LOUISVILLE MAG., Oct. 2012, at 16, 16 (“Approximately 75 percent of women in their 40s have dense breasts This percentage typically decreases with age, although close to half of all women in their 60s still have dense breast tissue.”).

¹²⁶ See DISCUSSING BREAST DENSITY, *supra* note 112, at 3.

¹²⁷ See Consumer Reports, *Some Cancer Screening Tests Are Worthwhile, but Others Are Rarely Warranted*, WASH. POST (Sept. 22, 2014), http://www.washingtonpost.com/national/health-science/some-cancer-screening-tests-are-worthwhile-but-others-are-rarely-warranted/2014/09/22/e135a334-0c47-11e4-b8e5-d0de80767fc2_story.html [<http://perma.cc/KDG7-6L95>] (noting that “[a] few years ago, women were usually told to get annual mammograms starting at age 40”).

have dense breasts.¹²⁸ Empowered with the knowledge that they have dense breasts, Ms. Cappello and fellow advocates believe that women will elect to undergo additional screenings.¹²⁹

Options for additional screenings have traditionally included a breast ultrasound or magnetic resonance imaging (MRI), which can sometimes detect tumors missed by traditional mammography.¹³⁰ Ultrasounds create images of the breast using high-frequency sound waves and can cost a couple of hundred dollars per screening.¹³¹ In contrast, a MRI can easily cost more than \$1,000.¹³² In addition, MRIs are time consuming; they can take up to an hour to perform.¹³³ The technology uses magnets and radio waves to provide cross-sectional images of the breast.¹³⁴

Recently, two new technologies have entered the market. Tomosynthesis is now covered by Medicare but is still rarely covered by insurers.¹³⁵ Approved in 2011 by the FDA, tomosynthesis “takes many X-rays at different angles to create a three-dimensional image of the breast.”¹³⁶ Only a small portion of mammographic centers offer tomosynthesis. As a consequence, it is not yet a widely available option for women.¹³⁷ Molecular breast imaging—or MBI—is also a promising new technology. MBI requires injecting patients with a radioactive tracer.¹³⁸ The cancer cells absorb the tracer and “light up” when viewed with a small camera.¹³⁹

¹²⁸ See Grady, *supra* note 46 (quoting Ms. Cappello: “I want to help other women. I can’t help myself. My cancer should have been detected at a much earlier stage.”).

¹²⁹ See *id.* (reporting that Cappello would have had supplemental screenings if she had been told that she had dense breasts).

¹³⁰ See, e.g., Wendie A. Berg et al., *Detection of Breast Cancer with Addition of Annual Screening Ultrasound or a Single Screening MRI to Mammography in Women with Elevated Breast Cancer Risk*, 307 JAMA 1394, 1394 (2012).

¹³¹ See Victoria Colliver, *Law May Encourage Mammogram Alternatives*, SFGATE, <http://www.sfgate.com/health/article/Law-may-encourage-mammogram-alternatives-3901022.php> [<http://perma.cc/HCF7-WA9Y>] (last updated Sept. 27, 2012) (noting that “automated ultrasound costs between \$180,000 and \$250,000—about half the price of a digital mammogram unit—and patients are typically charged \$200 to \$300 per screening if it’s not covered by insurance”).

¹³² See Beck, *supra* note 109.

¹³³ See ACS, MAMMOGRAMS, *supra* note 100, at 18.

¹³⁴ *Id.* at 17.

¹³⁵ See CTRS. FOR MEDICARE & MEDICAID SERVS., PREVENTIVE & SCREENING SERVS.—UPDATE—INTENSIVE BEHAVIORAL THERAPY FOR OBESITY, SCREENING DIGITAL TOMOSYNTHESIS MAMMOGRAPHY, AND ANESTHESIA ASSOCIATED WITH SCREENING COLONOSCOPY 5 (2013), <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8874.pdf> [<http://perma.cc/Z2VB-ZL3J>].

¹³⁶ Grady, *supra* note 110.

¹³⁷ *Id.* (noting that “[a]bout 1,100 of 13,500 mammography units in the United States perform tomosynthesis”).

¹³⁸ See Beck, *supra* note 109.

¹³⁹ *Id.*

In spite of the plethora of additional screening options, physician groups have not endorsed routine supplemental screenings for dense women. The American College of Obstetricians and Gynecologists does not recommend routine use of supplemental screening tests for “women with dense breasts who are asymptomatic and have no additional risk factors.”¹⁴⁰ The American College of Radiology’s position statement notes that “there is no randomized trial data that shows that adding either ultrasound or MRI to mammography screening saves lives.”¹⁴¹ Nonetheless, density advocates believe that dense women should have the opportunity to decide for themselves whether or not a supplemental screening is in their best interests. Of course, to even get to the point where a woman is having a conversation about supplemental screenings with her physician, she needs to be informed that she is dense. Thus, for advocates, empowering women begins with notifying women about their breast density.

III. PATIENT AUTONOMY

At its core, autonomy means self-rule.¹⁴² Although autonomy has deep roots in western philosophy,¹⁴³ patient autonomy is a relatively new concept. The Hippocratic tradition was based on a covenantal relationship between the physician and patient.¹⁴⁴ The patient was charged with obeying and trusting the physician who in turn was encouraged to aspire to personal virtues of holiness and purity.¹⁴⁵ In addition, physicians were expected to demonstrate “compassion, knowledge, and dedication to the patient’s welfare” and to follow professional ethics.¹⁴⁶ The American Medical Association’s first Code of Ethics in 1847 warned patients that their “obedience . . . to the prescriptions

¹⁴⁰ AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, MANAGEMENT OF WOMEN WITH DENSE BREASTS DIAGNOSED BY MAMMOGRAPHY, Committee Opinion No. 625, at 1 (Mar. 2015), <http://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co625.pdf?dmc=1&ts=20151025T0119315414> [<http://perma.cc/K7BV-HTDE>].

¹⁴¹ ACR Statement on Reporting Breast Density in Mammography Reports and Patient Summaries, AM. C. RADIOLOGY (Apr. 24, 2012), <http://www.acr.org/About-Us/Media-Center/Position-Statements/Position-Statements-Folder/Statement-on-Reporting-Breast-Density-in-Mammography-Reports-and-Patient-Summaries> [<http://perma.cc/A88W-UP6W>] [hereinafter ACR, *Reporting Breast Density*].

¹⁴² See Arthur Kuflik, *The Inalienability of Autonomy*, 13 PHIL. & PUB. AFF. 271, 272 (1984) (“To be ‘autonomous’ is (literally) to be self-legislating or self-regulating.”).

¹⁴³ See generally, e.g., IMMANUEL KANT, FOUNDATIONS OF THE METAPHYSICS OF MORALS (Robert Paul Wolff ed., Lewis White Beck trans., Bobbs-Merrill Co. 1969) (1785); JOHN STUART MILL, ON LIBERTY (David Bromwich & George Kateb eds., Yale Univ. Press 2003) (1859).

¹⁴⁴ See Danuta Mendelson, *Historical Evolution and Modern Implications of Concepts of Consent to, and Refusal of, Medical Treatment in the Law of Trespass*, 17 J. LEGAL MED. 1, 14 (1996) (“Central to a covenantal relationship is the ethical principle of trust with its corresponding duties and obligations.”).

¹⁴⁵ *Id.* at 12.

¹⁴⁶ *Id.*

of [their] physician should be prompt and implicit. [They] should never permit [their] own crude opinions . . . to influence [their] attention to [their physicians].”¹⁴⁷

Consent to medical treatment as a legal concept developed within the framework of the law of trespass. Two of the earliest cases to discuss the notion of informed consent involved female patients. In *Pratt v. Davis*,¹⁴⁸ which was decided in 1905, the court declared that “under a free government at least, the free citizen’s first and greatest right, which underlies all others—the right to the inviolability of his person . . . necessarily forbids a physician or surgeon . . . to violate without permission the bodily integrity of his patient.”¹⁴⁹ In *Pratt*, Mr. Davis placed his wife, Mrs. Davis, in a sanitarium for treatment for epilepsy.¹⁵⁰ While examining Mrs. Davis, Dr. Pratt found that her “uterus was small, that it was lacerated and pinched, and that the condition of the last inch of the rectum was bad.”¹⁵¹ Dr. Pratt performed an operation.¹⁵² Mrs. Davis returned home, but Dr. Pratt soon informed Mr. Davis that Mrs. Davis should return for further treatment.¹⁵³ When Mrs. Davis returned to the sanitarium, Dr. Pratt performed a hysterectomy on Mrs. Davis without informing her or her husband.¹⁵⁴

As a result, Mr. Davis, on behalf of his wife, filed an action of trespass against Dr. Pratt.¹⁵⁵ Dr. Pratt did not argue that he obtained consent.¹⁵⁶ In fact, he readily admitted that he did not obtain consent from Mrs. Davis.¹⁵⁷ He stated, “I worked her deliberately, systematically, taking chances which she did not realize the full aspect of, deliberately and calmly deceived the woman. That is, I did not tell her the whole truth.”¹⁵⁸ Instead, Dr. Pratt argued that it would be an injustice to hold him liable because he used his best efforts to heal Mrs. Davis. Dr. Pratt stated that, in his opinion, the surgery was “proper and essential to her welfare” and that “the employment of the physician or surgeon gives him implied license to do whatever in the exercise of his judgment may be necessary.”¹⁵⁹ He further argued that when a patient places herself under the care of a physician for treatment that “upon his authority, she thereby in

¹⁴⁷ Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL’Y 69, 73 (1994) (alterations in original) (quoting AM. MED. ASS’N, CODE OF ETHICS (1847)).

¹⁴⁸ *Pratt v. Davis*, 118 Ill. App. 161 (1905), *aff’d*, 79 N.E. 562 (1906).

¹⁴⁹ *Id.* at 166.

¹⁵⁰ *Id.* at 168.

¹⁵¹ *Id.*

¹⁵² *Id.* at 170.

¹⁵³ *Id.*

¹⁵⁴ *Pratt*, 118 Ill. App. at 171–72.

¹⁵⁵ *Id.* at 161–62.

¹⁵⁶ *Id.* at 170.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 166.

law consents that he may perform such operation as in his best judgment is proper and essential to her welfare.”¹⁶⁰

Similarly, in *Mohr v. Williams*, the patient sued her doctor for performing an operation without her consent.¹⁶¹ The physician had obtained consent to operate on her right ear but, while she was under anesthesia, decided to operate on her left ear because it looked more diseased.¹⁶² The physician argued that he should not be held liable because “plaintiff’s left ear was in fact diseased, in a condition dangerous and threatening to her health, [and] the operation was necessary.”¹⁶³

In both *Pratt* and *Mohr*, the physicians acted for the benefit of their patients. They approached patient care with the commonly held belief that “patients are neither emotionally nor intellectually equipped to play a significant role in decisions affecting their medical fate . . . and that disclosures of uncertainty, gloomy prognosis and dire risks often seriously undermine cure.”¹⁶⁴ The courts rejected the arguments made by the physicians and held that performing a surgery without obtaining the patient’s consent constituted a battery.¹⁶⁵ Thereafter, case law permitted recovery against physicians who failed to obtain consent prior to performing a medical procedure.

Under a theory of battery, the law places a narrow obligation on physicians to inform the patient about what the doctor plans to do.¹⁶⁶ Thus, when a physician performs a procedure without telling the patient basic details about the proposed treatment, courts treat the physician’s actions as nonconsensual contact amounting to a battery.¹⁶⁷ In order to prevail in a battery action premised on lack of consent, the plaintiff must prove that the physician performed a procedure without obtaining the patient’s consent.¹⁶⁸

¹⁶⁰ *Pratt*, 118 Ill. App. at 166.

¹⁶¹ *Mohr v. Williams*, 104 N.W. 12, 12–13 (Minn. 1905).

¹⁶² *Id.* at 13.

¹⁶³ *Id.* at 15.

¹⁶⁴ See Jay Katz, *Informed Consent—A Fairy Tale? Law’s Vision*, 39 U. PITT. L. REV. 137, 148 (1977).

¹⁶⁵ See *Mohr*, 104 N.W. at 16 (holding that the surgery was a “violent assault, not a mere pleasantry; and, even though no negligence is shown, it was wrongful and unlawful”); *Pratt*, 118 Ill. App. at 173.

¹⁶⁶ See *Slater v. Baker* (1767) 95 Eng. Rep. 860 (KB) [862] (stating that “indeed it is reasonable that a patient should be told what is about to be done to him, that he may take courage and put himself in such a situation as to enable him to undergo the operation”).

¹⁶⁷ See, e.g., *Cobbs v. Grant*, 502 P.2d 1, 7 (Cal. 1972) (explaining that “[w]here a doctor obtains consent of the patient to perform one type of treatment and subsequently performs a substantially different treatment for which consent was not obtained, there is a clear case of battery”); *Mohr*, 104 N.W. at 16 (holding that physician was liable for battery because consent to an operation on the patient’s right ear did not authorize surgery on the left ear); *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (stating that “the wrong complained of is not merely negligence,” but trespass of the body).

¹⁶⁸ See, e.g., *Cobbs*, 502 P.2d at 8 (noting that “in a battery count, . . . the patient must merely prove failure to give informed consent and a mere touching absent consent”).

For nearly the next fifty years, the duty of doctors was limited to getting basic consent for proposed treatments. The law did not begin to establish a duty upon physicians to procure informed consent from patients until the end of the 1950s.¹⁶⁹ This new notion of informed consent can be traced to the belief that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”¹⁷⁰ Modern informed consent cases are based on principals of negligence, although egregious cases may still be brought under a theory of battery.¹⁷¹

Sounding the cause of action in negligence rather than battery became more appealing to courts for a number reasons. First, when physicians are acting in good faith for the benefit of the patient, their conduct is not morally blameworthy.¹⁷² Second, in cases where the patient is alleging that she was not informed of the risks of treatments, the act complained of does not fall within the traditional notions of unconsented touching.¹⁷³ Finally, courts had concerns about whether a physician’s malpractice insurance provides coverage for an intentional act like battery.¹⁷⁴ For these reasons, there was discomfort with potentially forcing physicians to pay out-of-pocket for what was essentially, in the eyes of the court, a negligence claim.¹⁷⁵

The first modern case to fully embrace a cause of action for informed consent involved a plaintiff who had breast cancer.¹⁷⁶ Irma Natanson was diagnosed with breast cancer and had a radical mastectomy of her left breast.¹⁷⁷ As a precautionary measure, her physician also removed her

¹⁶⁹ See *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Ct. App. 1957) (discussing that physicians have an obligation to disclose what treatment is intended and information that addresses the question of whether or not the treatment should be provided).

¹⁷⁰ *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972) (alterations in original) (quoting *Schloendorff*, 105 N.E. at 93).

¹⁷¹ See, e.g., *Roberson v. Provident House*, 576 So. 2d 992, 994 (La. 1991) (finding that nurse committed a battery when she inserted an internal catheter despite the plaintiff advising her of previous bad experiences with catheters and begging her to stop); *Blanchard v. Kellum*, 975 S.W.2d 522, 522 (Tenn. 1998) (holding for plaintiff in an action alleging medical battery when doctor failed to obtain consent before attempting to extract all thirty-two of the plaintiff’s teeth).

¹⁷² See *Trogun v. Fruchtmann*, 207 N.W.2d 297, 313 (Wis. 1973) (“[T]he act complained of is surely not of an antisocial nature usually associated with the tort of assault and battery or battery. While the unauthorized removal of an organ yet fits the concept of battery, the failure to adequately advise of potential negative ramifications of a treatment does not.”).

¹⁷³ See *Cobbs*, 502 P.2d at 8 (“[T]he doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence.”).

¹⁷⁴ See *Trogun*, 207 N.W.2d at 313.

¹⁷⁵ *Id.*

¹⁷⁶ *Natanson v. Kline*, 350 P.2d 1093, 1095 (Kan. 1960).

¹⁷⁷ *Id.* at 1106.

fallopian tubes and ovaries.¹⁷⁸ Her surgeon referred her to Dr. Kline, the defendant, for radiation therapy to reduce the likelihood that the cancer would reoccur.¹⁷⁹ With Mrs. Natanson's consent, Dr. Kline ordered and oversaw administration of doses of cobalt radiation therapy.¹⁸⁰

As a result of the cobalt radiation therapy, the skin, flesh and muscles beneath Mrs. Natanson's left arm "sloughed away" and "ribs of her left chest were so burned that they became necrotic, or dead."¹⁸¹ Dr. Kline testified that he was "'taking a chance' with the treatment he proposed to administer."¹⁸² He also acknowledged that "such treatment involved a 'calculated risk' [and that] there was always a danger of injury in the treatment of cancer."¹⁸³ Dr. Kline never testified that he informed Mrs. Natanson of the risks associated with cobalt therapy.¹⁸⁴ Presumably, Dr. Kline believed that it was his job to weigh the risks and benefits of cobalt therapy and that it was the role of Mrs. Natanson to trust his advice. Mrs. Natanson requested that the jury be instructed that the "the relationship between physician and patient is a fiduciary one [that] requires the physician to make a full disclosure to the patient," and that failure to disclose hazards of particular medical treatment renders the doctor negligent.¹⁸⁵ The trial court refused the instruction and the jury rendered a verdict for the defendants.¹⁸⁶ Mrs. Natanson appealed. The Kansas Supreme Court held:

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise, the physician may not minimize the known dangers of a procedure . . . in order to induce his patient's consent.¹⁸⁷

Most importantly, the court in *Natanson* stressed that "[a] doctor might well believe that an operation or form of treatment is desirable or necessary but the law does not permit him to substitute his own judgment for that of the patient by any form of artifice or deception."¹⁸⁸

Thus, modern jurisprudence recognizes the right of patients to make self-directed choices about their course of treatment and medical care. In order to

¹⁷⁸ *Id.*

¹⁷⁹ *Id.* at 1095.

¹⁸⁰ *Id.* at 1095–96.

¹⁸¹ *Id.* at 1098 (quoting the trial court's summary of the pleadings for the jury instructions).

¹⁸² *Natanson*, 350 P.2d at 1100.

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* at 1099.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 1104 (quoting *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Ct. App. 1957)).

¹⁸⁸ *Natanson*, 350 P.2d at 1104.

facilitate patient autonomy, the law places a duty upon doctors to obtain “informed consent” prior to treatment. Truly informing patients about their diagnosis, all their risks factors, all possible risks of treatment, however remote, and treatment alternatives, would be an arduous and impossible task for physicians. Thus, most jurisdictions require physicians to inform patients of the relevant facts without which an informed choice would be impossible.¹⁸⁹

In a slight majority of jurisdictions, the content of disclosure is evaluated by what a reasonable physician would disclose.¹⁹⁰ Ultimately, informed consent jurisprudence seeks to ensure that patients who want to make autonomous decisions are given the information that they need by their physicians. For that reason, potential liability for failure to disclose is, in theory, supposed to deter physicians from failing to adequately disclose relevant information to their patients. Despite the specter of a lawsuit, women have struggled to get information from their physicians about breast cancer.¹⁹¹ Early breast cancer advocates fought for information about treatment options.¹⁹² Namely, they wanted to ensure that women were making an informed choice between mastectomy and a lumpectomy, which preserves the breast but has a slightly higher rate of recurrence.¹⁹³ Similarly, dense women want to ensure that women are making an informed choice with respect to utilizing screening mammograms or other screening technology. They want

¹⁸⁹ See Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J. L. & MED. 429, 430 (2006).

¹⁹⁰ See, e.g., *Craig v. Borcicky*, 557 So. 2d 1253, 1258 (Ala. 1990); *Eady v. Lansford*, 92 S.W.3d 57, 60 (Ark. 2002); *Fuller v. Starnes*, 597 S.W.2d 88, 89–90 (Ark. 1980); *Shabinaw v. Brown*, 963 P.2d 1184, 1188–94 (Idaho 1998); *Ziegert v. S. Chi. Cmty. Hosp.*, 425 N.E.2d 450, 458–59 (Ill. App. Ct. 1981); *Culbertson v. Mernitz*, 602 N.E.2d 98, 101, 103–04 (Ind. 1992); *Woolley v. Henderson*, 418 A.2d 1123, 1128–31 (Me. 1980); *Paul v. Lee*, 568 N.W.2d 510, 513–14 (Mich. 1997); *Walls v. Shreck*, 658 N.W.2d 686, 690 (Neb. 2003); *Weber v. McCoy*, 950 P.2d 548, 552 (Wyo. 1997). Alternatively some jurisdictions require that doctors make disclosures based on what a “reasonable patient” would find significant. See, e.g., *Carr v. Strode*, 904 P.2d 489, 494–99 (Haw. 1995); *Rook v. Trout*, 747 P.2d 61, 66–67 (Idaho 1987); *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 361–62 (Iowa 1987); *Harnish v. Children’s Hosp. Med. Ctr.*, 439 N.E.2d 240, 242–44 (Mass. 1982); *Phillips v. Hull*, 516 So. 2d 488, 493–94 (Miss. 1987); *Wilkinson v. Vesey*, 295 A.2d 676, 688–90 (R.I. 1972); *Wheeldon v. Madison*, 374 N.W.2d 367, 374–75 (S.D. 1985).

¹⁹¹ Breast cancer advocates believed that their struggle to get adequate information was because of their sex. See Montini, *supra* note 39, at 92 (explaining that because “the majority of physicians who treated breast cancer were men, and the patients primarily women, sexism was disabling the system . . . [and w]omen advocated for legislative action to protect them as a special class of patients”).

¹⁹² See E. Dale Collins et al., *Can Women with Early-Stage Breast Cancer Make an Informed Decision for Mastectomy?*, 27 J. CLINICAL ONCOLOGY 519, 524 (2009).

¹⁹³ See Montini, *supra* note 39, at 90–91 (noting that breast cancer advocates were alarmed at the high rates of masectomy in spite of the fact that survival rates for lumpectomies were the same).

women to be given information about their breast density and to appreciate and understand the limitations of mammography.

A. Legislating a Standard Notification

The undisputed goal of dense breast tissue notification legislation is to empower women. The stories of dense women are all remarkably similar. After years of having regular mammograms, no single doctor had ever bothered to tell them that they had dense breasts until after they were diagnosed with advanced breast cancer.¹⁹⁴ Thus, these dense women had no idea that the density of their breast tissue could obscure cancer on their mammogram, and they did not know that more sensitive screenings could potentially find tumors missed by the mammogram. According to density advocate Salmeron of Texas, this was inexcusable.¹⁹⁵

The remedy of course is obvious. For dense breast tissue advocates, women have a right to know if they have dense breast tissue so that they can seek out supplemental screenings. Thus, the power is derived not simply from being given knowledge, but equally from having the ability to act on that knowledge.¹⁹⁶ Nancy Cappello, the founder of Are You Dense Advocacy, rather succinctly states that density notification laws “give consumers information about the limitations of mammography to detect cancer while promoting conversations about personalized screening surveillance with health-care providers. Women then become the boss of their breasts.”¹⁹⁷

Unsurprisingly, the medical community has not warmly embraced density notification laws. Some doctors have complained that the law will “provoke anxiety” in women¹⁹⁸ and “may confuse women, scare some needlessly.”¹⁹⁹ On the surface, these arguments seem reminiscent of the arguments forty years ago when physicians wanted to choose radical mastectomy for their women patients without giving them adequate options.²⁰⁰ Such arguments seem paternalistic and fail to recognize the right of women to make autonomous decisions about their health. However, not all arguments against the

¹⁹⁴ See *supra* pp. 856–60 (discussing the stories of density advocates).

¹⁹⁵ See *supra* p. 858.

¹⁹⁶ See Nancy M. Cappello, *Who's the Boss of Our Breast Health Information?*, HUFFINGTON POST (Dec. 17, 2014), http://www.huffingtonpost.com/nancy-m-cappello/whos-the-boss-of-our-brea_b_6319718.html [<http://perma.cc/Z6S8-L4YX>] (noting that “[p]atients can only act on what their doctor chooses to disclose”).

¹⁹⁷ *Id.*

¹⁹⁸ See Mary Ann Roser, *New Texas Law Informs Women of a Possible Cancer Risk from Dense Breasts*, AUSTIN AM.-STATESMEN (Nov. 9, 2011), <http://www.statesman.com/news/lifestyles/health/new-texas-law-informs-women-of-a-possible-cancer-r/nRg4Z/> [<http://perma.cc/L59M-73NS>] (reporting that “[s]ome doctors said they worry it will provoke anxiety and lead to more costly MRIs”).

¹⁹⁹ See Grady, *supra* note 46.

²⁰⁰ See Montini, *supra* note 39, at 93–96 (discussing physician resistance to disclosing treatment options to women with breast cancer).

notifications are blatantly paternalistic. Some medical professionals have opposed the legislation on grounds that density notification laws will prompt too many referrals for costly supplemental screenings which have high false-positive rates.²⁰¹ A recent study estimated that for every 10,000 dense women between the ages of fifty and seventy-four screened with a supplemental ultrasound that about four breast cancer deaths would be prevented, but an extra 3,500 biopsies would also be performed.²⁰² In any event, just like the generation of women before them, dense women seek a legislative remedy in order to overcome the long-standing physician temptation to withhold information from women.

For density notification advocates, notification laws open the door for women to have a more informed conversation with her physician about possible next steps.²⁰³ Advocates believe that women can evaluate the pitfalls of supplemental screenings and should be given the opportunity to make the right decision for themselves. Thus, density notification statutes compel physicians to disclose breast density information in the lay summary of the mammogram report.

Disclosure of this information is seemingly not a departure from the ideals annunciated in *Natanson* and its progeny. The law clearly recognizes that patients should be provided with risk information by physicians. The major risk of dense breast tissue is that it can obscure cancer. Thus, it seems obvious that women who receive mammograms and who have dense breast tissue should be alerted to this fact. In almost every state that has passed density legislation, women have angrily told lawmakers that they should have been told that they had dense breasts before, ultimately, being diagnosed with breast cancer.²⁰⁴ Their anger at being kept in the dark by their physicians has fueled their desire to help other women by ensuring that women are told when they

²⁰¹ See Slanetz et al., *supra* note 115, at 594 (noting that the high false positive rates suggest that “supplemental screening unnecessarily increases rates of biopsy, costs, and patients’ anxiety”).

²⁰² See Brian L. Sprague et al., *Benefits, Harms, and Cost-Effectiveness of Supplemental Ultrasonography Screening for Women with Dense Breasts*, 162 ANNALS INTERNAL MED. 157, 159–60 (2015).

²⁰³ Roser, *supra* note 198 (quoting State Rep. Ana Hernandez Lunda, author of the Texas density notification statute: “This allows one, for the patient to become aware of this issue and two, allows them to take steps to discuss with their physician just exactly what that means in each woman’s case. It serves as a way to open dialogue with their physician . . .”).

²⁰⁴ For example, in Ohio, Anne Gates testified in favor of the density notification law. Gates fought for the legislation after she was not told that she had dense breasts until being diagnosed with late stage breast cancer. See Angela Townsend, *Ohio Is 20th State with Breast Density Notification Law; Requires Women to Be Told After Mammogram*, CLEVELAND.COM (Jan. 13, 2015), http://www.cleveland.com/healthfit/index.ssf/2015/01/ohio_is_20th_state_with_breast_density_notification_law_requires_women_to_be_told_following_mammogram.html [<http://perma.cc/8AGV-4JS9>]; see also Grady, *supra* note 46; Harmon, *supra* note 67; Pearson, *supra* note 58.

have dense breasts. There can be little doubt that disclosing information about breast density to women empowers them.

B. Undermining Women

While the desire to inform women about breast density is laudable, as currently implemented, most notification laws undermine women rather than empower them. States have taken four approaches in drafting the required notification: (1) directive; (2) moderately directive; (3) mildly directive; and (4) neutral. As will be discussed, the highly directive and moderately directive approaches usurp the power of women to make independent unbiased choices about their medical care. While all the statutes purport to empower women, in practice, directive statutes to varying degrees direct women towards a specific path. In other words, states that utilize directive dense breast notifications are nudging, prodding, or pushing women to act. Even more troubling, they are pushing women towards supplemental testing without requiring insurers to pay for it. Only two states with density notification laws, Connecticut²⁰⁵ and New Jersey²⁰⁶ also mandate that insurers pay for supplemental screenings for women with dense breasts.

Table 1: *Notification Differences by State*

	Notification Type			
	Neutral	Mildly Directive	Moderately Directive	Highly Directive
Alabama				X
Arizona			X	
California			X	
Connecticut		X		
Delaware			X	
Hawaii				X
Maryland			X	
Massachusetts				X
Michigan				X
Minnesota			X	
Missouri		X		
Nevada		X		

²⁰⁵ See CONN. GEN. STAT. ANN. § 38a-503(a)(2)(A) (West 2012).

²⁰⁶ See N.J. STAT. ANN. §§ 17:48-6g(a)(2), :48E-35.4(a) (West Supp. 2015).

	Notification Type			
	Neutral	Mildly Directive	Moderately Directive	Highly Directive
New Jersey			X	
New York				X
N. Carolina			X	
N. Dakota	X			
Ohio	X			
Oregon			X	
Pennsylvania			X	
Rhode Island			X	
Tennessee			X	
Texas		X		
Virginia				X

1. *Highly Directive Notifications*

Alabama,²⁰⁷ Hawaii,²⁰⁸ Massachusetts,²⁰⁹ Michigan,²¹⁰ New York,²¹¹ and Virginia²¹² require that patients be provided with a highly directive breast density notification. For example Alabama's statute directs physicians to include the following statement:

Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, dense breast tissue may make it harder to find cancer on a mammogram and may also be associated with an increased risks of breast cancer. This information about the result of your mammogram is given to you to raise your awareness. Use this information to talk to your doctor about your own risks for breast cancer. At that time, ask your doctor if more screening tests might be useful, based on your risk. A report of your results was sent to your physician.²¹³

This approach is characterized as highly directive because the notification informs women of the risks associated with breast density and directs women

²⁰⁷ See ALA. CODE § 22-13-71(a) (LexisNexis Supp. 2014).

²⁰⁸ See HAW. REV. STAT. ANN. § 321-46(a) (West Supp. 2014).

²⁰⁹ See MASS. ANN. LAWS ch. 111, § 5Q(b) (LexisNexis Supp. 2015).

²¹⁰ See MICH. COMP. LAWS ANN. § 333.13524(1) (West Supp. 2015).

²¹¹ See N.Y. PUB. HEALTH LAW § 2404-c (McKinney Supp. 2015).

²¹² See VA. CODE ANN. § 32.1-229 (Supp. 2015).

²¹³ ALA. CODE § 22-13-71(a) (LexisNexis Supp. 2014).

to “use” the information provided about dense breast tissue to “ask” her doctor if more screening tests might be useful. Thus, highly directive notifications go beyond informing women that dense breast tissue may obscure cancer on mammograms. These statutes dictate to women how they should use the information given.²¹⁴

States which utilize highly directive notifications have replaced paternalistic doctors, who withhold information from their women patients, with legislative edicts that adjure women to ask their physicians about additional screenings. Such statutes do not empower women, they undermine women. States which choose to inform and command woman are substituting the judgment of legislators for the judgment of women. Legislators are predetermining for women how they should use risk information about dense breast tissue. This undermines patient autonomy, albeit this time at the hands of the legislature.

2. Moderately Directive Notifications

Moderately directive notification statutes are less paternalistic than the highly directive variety. Arizona,²¹⁵ California,²¹⁶ Delaware,²¹⁷ Maryland,²¹⁸ Minnesota,²¹⁹ New Jersey,²²⁰ North Carolina,²²¹ Oregon,²²² Pennsylvania,²²³ Rhode Island,²²⁴ and Tennessee²²⁵ require moderately directive dense breast tissue notifications. Arizona’s statute is illustrative of the path followed by most moderately directive notification. The statute requires that patients receive the following notice:

Your mammogram indicates that you have dense breast tissue. Dense breast tissue is common and is found in fifty per cent of women. However, dense breast tissue can make it more difficult to detect cancers in the breast by mammography and may also be associated with an increased risk of breast cancer. This information is being provided to raise your awareness and to encourage you to discuss with your health care providers your dense breast

²¹⁴ Massachusetts’ notification requirements are also highly directive. However unlike the other states Massachusetts provides a list of elements which should be included in the notification instead mandating the use of specific language. *See* MASS. ANN. LAWS ch. 111, § 5Q(b) (LexisNexis Supp. 2015).

²¹⁵ *See* ARIZ. REV. STAT. ANN. § 36-415(A) (Supp. 2014).

²¹⁶ *See* CAL. HEALTH & SAFETY CODE § 123222.3(a) (West Supp. 2015).

²¹⁷ *See* DEL. CODE ANN. tit. 16, § 3201A(a) (West, Westlaw through 80 Laws 2015, ch. 193).

²¹⁸ *See* MD. CODE ANN., HEALTH-GEN. § 20-115(c)(2) (LexisNexis Supp. 2014).

²¹⁹ *See* MINN. STAT. ANN. § 144.1212(2) (West Supp. 2015).

²²⁰ *See* N.J. STAT. ANN. § 26:2-184.3 (West Supp. 2015).

²²¹ *See* N.C. GEN. STAT. § 130A-215.5(a) (2013).

²²² *See* OR. ADMIN. R. 333-106-0735 (2015).

²²³ *See* 35 PA. STAT. AND CONS. STAT. ANN. § 10229.2(b) (West Supp. 2015).

²²⁴ *See* 23 R.I. GEN. LAWS § 23-12.9-2 (Supp. 2014).

²²⁵ *See* TENN. CODE ANN. § 63-6-245(b) (Supp. 2014).

tissue and other breast cancer risk factors. Together, you and your physician can decide if additional screening options are right for you. A report of your results was sent to your physician.²²⁶

Moderately directive statutes inform women of the risks associated with breast cancer. In addition, these statutes explicitly contemplate that women will use the provided information to make an informed choice about additional screenings with the aid of her physician. Moderately directive statutes conceive of a world in which all women value shared decision-making with their doctors. These statutes embrace the ideals exposed by the informed consent jurisprudence.

However, true autonomy is self-directed. Not every individual desires to participate in a shared-decision making with their physician. Studies have shown that different racial and ethnic groups view medical decision making differently. For example, one study, which examined patient preferences, found that African-American and Hispanic patients were more likely to prefer that physicians make medical decisions for them.²²⁷ This same study also found that more affluent patients tend to have a strong preference for having an active role in medical decision making.²²⁸ Another famous study by Dr. Leslie Blackhall found that non-European ethnic groups often do not value individual autonomy when making medical decisions to the same degree as their European counterparts.²²⁹ Blackhall found that “[a]utonomy is not viewed as empowering. Rather, it is seen as isolating and burdensome to patients”²³⁰ Further, in another study of African-American patients, researchers found that nearly half of African-American patients wanted their provider to make medical decisions for them.²³¹

Combined, these studies call into question whether assuming that constituents want to participate in shared decision-making is wise. Density notification advocates are strikingly similar. The advocates tend to be middle-aged, middle to upper-middle class white women. Yet, the legislation affects all women. In our pluralistic society, there are substantial segments of the patient population who do not identify dominant values as their own.²³² Presuming a preference for shared decision-making, undermines women who

²²⁶ ARIZ. REV. STAT. ANN. § 36-415(A) (Supp. 2014).

²²⁷ See, e.g., Wendy Levinson et al., *Not All Patients Want to Participate in Decision Making: A National Study of Public Preferences*, 20 J. GEN. INTERNAL MED. 531, 533 (2005).

²²⁸ *Id.* at 531.

²²⁹ See Leslie Blackhall et al., *Ethnicity and Attitudes Toward Patient Autonomy*, 274 JAMA 820, 824 (1995).

²³⁰ *Id.*

²³¹ See Alexia M. Torke et al., *African American Patients' Perspectives on Medical Decision Making*, 164 ARCHIVES INTERNAL MED. 525, 528 (2004).

²³² Even when researchers have studied decision making in mostly white women, they have found distinct preferences. See, e.g., Penny F. Pierce, *Deciding on Breast Cancer Treatment: A Description of Decision Behavior*, 42 NURSING RES. 22, 25 (1993).

prefer to leave medical decision making in the exclusive hands of their physician.

3. *Mildly Directive Notifications*

Connecticut,²³³ Missouri²³⁴, Nevada²³⁵, and Texas,²³⁶ require a mildly directive density notification. Mildly directive density notification statutes inform women that having dense breasts may obscure breast cancer. In addition, these notifications alert women to the fact that supplemental screenings may be suggested by their physician and may be beneficial. For example, Missouri's statute requires the following notice:

If your mammogram demonstrates that you have dense breast tissue, which could hide abnormalities, and you have other risk factors for breast cancer that have been identified, you might benefit from supplemental screening tests that may be suggested by your ordering physician. Dense breast tissue, in and of itself, is a relatively common condition. Therefore, this information is not provided to cause undue concern, but rather to raise your awareness and to promote discussion with your physician regarding the presence of other risk factors, in addition to dense breast tissue. A report of your mammography results will be sent to you and your physician. You should contact your physician if you have any questions or concerns regarding this report.²³⁷

Unlike the moderately directive notifications, mildly directive notifications do not presume shared decision-making. Instead, mildly directive notifications “promote discussion.” The discussion that mildly directive statutes seem to promote is, however, directed. The average person receiving the notice would assume that a discussion with their physician about supplemental screening is forthcoming. If the physician fails to discuss the issue, then the notification has at least flagged the issue for women. Unlike, the moderately directive or highly directive notifications, the mildly directive density notifications empower women without strongly suggesting a predetermined outcome.

4. *Neutral Notifications*

While mildly directive density notifications can be said to nudge women to discuss supplemental screening options with their physicians, neutral notifications advise women that dense breast tissue can obscure cancer without

²³³ CONN. GEN. STAT. ANN. § 38a-503(c) (West 2012).

²³⁴ MO. ANN. STAT. § 192.769(1) (West Supp. 2015).

²³⁵ NEV. REV. STAT. ANN. § 457.1857(4) (LexisNexis Supp. 2013).

²³⁶ TEX. HEALTH & SAFETY CODE ANN. § 86.013(a) (West Supp. 2014).

²³⁷ MO. ANN. STAT. § 192.769(1).

suggesting supplemental screenings. North Dakota²³⁸ and Ohio²³⁹ are the only two states that have adopted this approach. The North Dakota statute requires a notice stating that “the patient has dense breast tissue, that this dense breast tissue may make it more difficult to detect cancer on a mammogram, and that this dense breast tissue may increase the patient’s risk of breast cancer.”²⁴⁰

This language is completely non-directive. It does not direct a woman to engage in a discussion with her physician nor does it suggest that a supplemental screening may be necessary. The language required by the North Dakota merely provides information about breast density and allows the dense woman to determine what, if anything, she should do with that information.

The language required by Ohio is slightly more directive. The Ohio statute requires the following notice:

Your mammogram demonstrates that you have dense breast tissue, which could hide abnormalities. Dense breast tissue, in and of itself, is a relatively common condition. Therefore, this information is not provided to cause undue concern; rather, it is to raise your awareness and promote discussion with your health care provider regarding the presence of dense breast tissue in addition to other risk factors.²⁴¹

The Ohio statute requires language that raises awareness of the fact that dense breast tissue can obscure cancer and seeks to promote discussion of risk factors. The Ohio statute does not direct the patient’s attention to supplemental screenings, endorse a vision of shared decision-making, or command recipients to ask specific questions of their physicians. However, it does explicitly state a goal of promoting discussion.

In interviews, the advocates have uniformly expressed anger over having undergone yearly mammograms and never having been told that they had dense breasts which could obscure cancer. The neutral approach and mildly directive approaches address the underlying frustration of breast density notification advocates without unduly trampling upon women who do not want to be proactive participants in their healthcare. In order to truly empower women, legislation must allow women to define the terms under which she makes healthcare decisions. Legislatively manipulated healthcare decisions are just as problematic as physicians making treatment decisions that do not reflect the wishes of their female patients. In order to show respect for all constituents, legislators should not adopt moderately directive or highly directive notification provisions.

²³⁸ N.D. CENT. CODE § 23-01-43 (Supp. 2015).

²³⁹ OHIO REV. CODE ANN. § 3702.40(B) (West Supp. 2015).

²⁴⁰ N.D. CENT. CODE § 23-01-43(2) (Supp. 2015).

²⁴¹ OHIO REV. CODE ANN. § 3702.40(B) (West Supp. 2015).

IV. PHYSICIAN AUTONOMY

Physicians, researchers, and legislators have long complained that the omnipresent fear of a lawsuit forces physicians to practice defensive medicine.²⁴² Physicians commonly report ordering extra tests, performing unnecessary procedures, and adding additional layers of documentation in order to reduce the risk of lawsuit or facilitate a defense if a medical malpractice claim is filed.²⁴³ Density notification statutes put pressure on physicians to order supplemental screenings for women who have dense breast in spite of the fact that there is no scientific evidence that such screenings are beneficial to most dense women.²⁴⁴ There is little question that the density notification language alters the standard of care by nudging physicians to order supplemental screenings.

A. *Legislating a Standard of Care*

All of the approaches to density notifications, except for the neutral approach which Ohio uses, to varying degrees alert patients to existence of supplemental screenings and direct women to ask their physicians about them.²⁴⁵ In the face of women asking questions about tests, the number of referrals will undoubtedly increase. Therefore, Donna Montalto, executive director of the American College of Obstetricians and Gynecologists' New York chapter, opposes density notification legislation. She believes that the legislation will cause OB-GYNs to recommend ultrasounds not because they are medically necessary "but mainly because of the threat of malpractice suits if breast cancer is missed . . . [t]hat's defensive medicine."²⁴⁶ The inherent

²⁴² See generally U.S. CONG., OFFICE OF TECH. ASSESSMENT, DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE (July 1994), <http://biotech.law.lsu.edu/policy/9405.pdf> [<http://perma.cc/E442-4GPL>].

²⁴³ See Randall R. Bovbjerg, *Beyond Tort Reform: Fixing Real Problems*, 3 IND. HEALTH L. REV. 3, 11–12 (2006); see also J. William Thomas et al., *Low Costs of Defensive Medicine, Small Savings from Tort Reform*, 29 HEALTH AFF. 1578, 1578 (2010) (noting that "[a] distinction is sometimes made between 'positive' defensive medicine—extra tests or procedures performed primarily to reduce malpractice liability—and 'negative' defensive medicine, by which physicians avoid treating high-risk patients, performing high-risk procedures, or practicing in certain geographic areas because of fear of potential malpractice litigation").

²⁴⁴ See Sprague et al., *supra* note 202, at 161–63 (finding that supplemental ultrasonography screenings for women with dense breasts has a high false-positive rate and substantially increases the number of unnecessary biopsies with little gain in quality-adjusted life years).

²⁴⁵ For a discussion of the various state approaches to density notification, see *supra* Part III.B.

²⁴⁶ See Beck, *supra* note 48; see also Carol H. Lee, *Dense Breast Tissue and Screening*, RADIOLOGY TODAY, Jan. 2014, at 30, <http://www.radiologytoday.net/archive/rt0114p30.shtml> [<http://perma.cc/K38N-HZJP>] ("Rather than having a discussion and weighing all the different factors, they're just saying, 'You have dense tissue; go get an

danger with density notification legislations is that it moves the standard of care towards practicing defensive (i.e., legislatively prescribed) medicine instead of encouraging physicians to utilize evidence based decision-making.

1. *Medical Malpractice*

Medical malpractice is the vehicle through which physicians are held accountable for their carelessness to their patients. It is of course an always present deterrence to commit errors.²⁴⁷ With nearly 200,000 women being diagnosed with breast cancer each year, the failure to diagnose breast cancer is the basis for more medical malpractice claims than any other disease in this country.²⁴⁸

To establish medical malpractice or negligence, one must prove a (1) preexisting duty owed to the patient, (2) that the duty was breached, (3) that the breach of duty caused (4) the patient's harm.²⁴⁹ The duty is typically established by the provider-patient relationship. In most negligence cases other than medical malpractice, defendants are judged based on what a reasonable person would have done under similar circumstances,²⁵⁰ and compliance with custom is a simply one factor for the jury to consider.²⁵¹ In contrast, physicians set their own standard of care, which is based on customary practice.²⁵²

Thus, for medical malpractice cases, the customary and usual performance of a physician under similar circumstances constitutes the benchmark for

ultrasound' or 'Go get an MRI.' I don't think that's ideal, but I think it's one of the unavoidable consequences of direct density notification.").

²⁴⁷ See CHARLES KRAMER, *THE NEGLIGENT DOCTOR* 17 (1968); Jennifer Arlen, *Contracting over Liability: Medical Malpractice and the Cost of Choice*, 158 U. PA. L. REV. 957, 959 (2010) (noting that "[m]alpractice liability is potentially one of the most effective mechanisms for reducing medical error").

²⁴⁸ See Gary Hillerich et al., *Selecting and Presenting a Failure to Diagnose Breast Cancer Case*, 20 AM. J. TRIAL ADVOC. 253, 253-54 (1996-97).

²⁴⁹ See Bryan A. Liang, *Medical Malpractice: Do Physicians Have Knowledge of Legal Standards and Assess Cases as Juries Do?*, 3 U. CHI. L. SCH. ROUNDTABLE 59, 59-60 (1996).

²⁵⁰ See RESTATEMENT (SECOND) OF TORTS § 283 (AM. LAW INST. 1965) ("[T]he standard of conduct to which he must conform to avoid being negligent is that of a reasonable man under like circumstances."); *Negligence*, BLACK'S LAW DICTIONARY (10th ed. 2014) (defining "negligence" as the "failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation").

²⁵¹ See RESTATEMENT (SECOND) OF TORTS § 295A (AM. LAW INST. 1965) (stating that custom is a factor but not controlling in the determination of whether an actor is negligent).

²⁵² See, e.g., Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 163 (2000) ("While defendants in ordinary tort actions are expected to exercise reasonable care under the circumstances, physicians traditionally have needed only to conform to the customs of their peers.").

determining whether the physician was negligent or not.²⁵³ Thus, the jury's inquiry is positive instead of normative. The jury is charged with determining what customary medical practice is and is not charged with determining what custom ought to be.²⁵⁴ Clarence Morris, in his widely cited article, *Custom and Negligence*, opined that neither the judge nor the jury is "competent to judge whether or not a doctor has acted reasonably."²⁵⁵

In medical malpractice cases, physician expert witnesses are critical. The plaintiff's expert or experts must explain what the standard of care is and how the defendant deviated from the standard of care. Often the most challenging part of the case is establishing a causal connection between the defendant's deviation from the standard of care and the harm suffered by the plaintiff.

Borgren is illustrative of the challenges that the average plaintiff faces.²⁵⁶ Margaret Borgren, the plaintiff, was a fifty-two-year-old married mother of eight, who had regular biannual screening mammograms.²⁵⁷ Borgren received all of her care through Irwin Army Hospital, a veteran's hospital. Her first screening mammogram occurred in June of 1980.²⁵⁸ The report suggested a "slight asymmetry" and suggested a six-month follow-up.²⁵⁹ Borgren did not follow-up at six months. Her next mammograms occurred in 1983 and 1985.²⁶⁰ The mammogram reports noted a benign calcification of the left breast and no other changes.²⁶¹ In 1986, Borgren had a fourth mammogram after performing a self-examination and finding a lump in her left breast.²⁶² This time her mammogram was performed at Vail Regional Medical Center.²⁶³ Her 1986 mammography report noted an architectural distortion in the left breast, which lead to her cancer diagnosis.²⁶⁴

Soon after her 1986 mammogram, Borgren underwent a modified radical mastectomy for Stage II infiltrating ductal and lobular carcinoma with sixteen of twenty-six nodes positive for tumor.²⁶⁵ Borgren sued the radiologist for malpractice arguing loss of chance of survival related to misdiagnosis and failure to suggest biopsy after the 1983 and 1985 mammograms.²⁶⁶ Borgren's

²⁵³ See James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1384 (1994).

²⁵⁴ See Phillip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 920 (2002).

²⁵⁵ Clarence Morris, *Custom and Negligence*, 42 COLUM. L. REV. 1147, 1164 (1942).

²⁵⁶ *Borgren v. United States*, 716 F. Supp. 1378 (D. Kan. 1989).

²⁵⁷ *Id.* at 1380.

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² *Borgren*, 716 F. Supp. at 1380.

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ *Id.*

²⁶⁶ *Id.* at 1379–80.

expert testified that the malignancy had been present on the 1983, 1985, and 1986 mammograms and that the delay in diagnosis reduced Borgren's chance of survival by 30-57% over ten years.²⁶⁷ This determination was based on a complex formula which included tumor doubling time and nodal status.²⁶⁸ Further, Borgren's expert estimated that in 1983 only one to three lymph nodes were cancerous.²⁶⁹ The defendant's expert challenged the standard of care that was asserted by Borgren's expert and suggested that assuming that only one to three lymph nodes were cancerous in 1983 was mere speculation.²⁷⁰

The court in *Borgren* found that the radiologist's negligence caused: (a) a three-year delay in the diagnosis of Borgren's breast cancer; (b) an increase in the number of nodes affected, as only one to three nodes were estimated to be affected in 1983 while sixteen to twenty-six were cancerous in 1986; and (c) loss of lumpectomy or breast conserving surgery as an option.²⁷¹ Borgren was awarded \$800,000 in damages for the decrease chance of survival, pain, suffering, mental anguish, and disfigurement.²⁷² The trial court reduced her award by 10% for comparative negligence.²⁷³

Borgren, like many breast cancer cases, is premised on a theory of loss-of-a-chance stemming from a misdiagnosis.²⁷⁴ The causation element in loss-of-a-chance cases is proven when "the evidence has established the patient had an appreciable chance to survive if given proper treatment."²⁷⁵ Thus, in loss-of-a-chance cases, the plaintiff does not allege that the physician caused the cancer. Instead, the patient argues that the physician's inaction precluded early diagnosis and treatment, which increases the rate of recurrence or shortens the patient's expected life span.

This type of argument is well-suited in the density notification context. The dense woman's argument would be straightforward. First, she would argue that the by virtue of the doctor-patient relationship that the radiologist owed her a duty. Second, she would allege that failure to notify or diagnoses her dense breasts fell below the standard of care. Third, the patient would argue that failure to alert her of her dense breast caused harm because she was deprived of the opportunity to undergo supplemental screenings, which would have been able to detect the cancer. Finally, she would allege damages. The

²⁶⁷ *Id.* at 1382.

²⁶⁸ *Borgren*, 716 F. Supp. at 1380.

²⁶⁹ *Id.* at 1382.

²⁷⁰ *Id.*

²⁷¹ *Id.* at 1382-83.

²⁷² *Id.* at 1384.

²⁷³ *Id.*

²⁷⁴ See, e.g., *Sawhani v. Mills*, 830 N.E.2d 932, 935-37 (Ind. Ct. App. 2005); *Renzi v. Paredes*, 890 N.E.2d 806, 809-12 (Mass. 2008); *Mancuso v. Neckles ex rel. Neckles*, 747 A.2d 255, 257 (N.J. 2000); *Davison v. Rini*, 686 N.E.2d 278, 280-81 (Ohio Ct. App. 1996); *Carrozza v. Greenbaum*, 866 A.2d 369, 374-76 (Pa. Super. Ct. 2004).

²⁷⁵ See *Borgren*, 716 F. Supp. at 1381.

most likely damages include shortened lifespan, pain and suffering linked to aggressive chemotherapy treatments, lost wages, and emotional distress.

For radiologists, establishing breast density is not a simple task. While some statutes explicitly state the notification should be sent to women with “heterogeneously dense” and “extremely dense” breasts as defined by the American College of Radiology,²⁷⁶ other states do not provide guidance on determining when a woman has sufficiently dense breast to require a notification.²⁷⁷ Diagnosing dense breast tissue is not black and white like diagnosing high blood pressure or high cholesterol. Sometimes what constitutes a dense breast varies widely because the reading is typically subjective.²⁷⁸ Most radiologists estimate breast density based on visual judgments, but recently, some radiologists have begun using computer software to help provide greater consistency across patients.²⁷⁹

As a result of breast density notification statutes, the standard of care for a radiologist is set in part by the legislature. This fact was not completely lost on state legislators. Consequently, some states address the scope of civil liability in the density notification statute. For example, the Tennessee statute states that the notification provisions do not “create a duty of care or other legal obligation.”²⁸⁰ Maryland²⁸¹ and Texas²⁸² also have similar statutory provisions.

The practical effect of such language is unclear. In medical malpractice cases, the standard of care is determined by reference to customary practices of physicians within the same specialty. One can reasonably assume that it is customary for physicians to follow the law. Thus, by requiring physicians to disclose notice of breast density, the legislature is setting the standard of care. It would be most unusual if medical custom routinely thwarted the law. While state legislatures have not explicitly set the standard of care for physicians, the law compels physicians to comply and compliance with the law becomes the standard of care.

²⁷⁶ For example, Alabama, Arizona, California, Hawaii, Michigan, Minnesota, New York, North Carolina, Oregon, Rhode Island, Tennessee, and Virginia clearly require that density notifications only be sent to women with heterogeneously dense or extremely dense tissue.

²⁷⁷ Connecticut, Massachusetts, Ohio, and Rhode Island requires notifications to women with dense breasts without defining the category of density.

²⁷⁸ See Lee, *supra* note 246.

²⁷⁹ See Beth W. Orenstein, *Breast Density—How Breast Imagers Put Notification and Screening into Practice*, RADIOLOGY TODAY, Apr. 2014, at 18, <http://www.radiologytoday.net/archive/rt0414p18.shtml> [<http://perma.cc/3TF9-PMBZ>] (noting that the software systems being implemented calculate density differently: Volpara uses a volumetric approach to establishing breast density and VuComp uses advanced computer vision algorithms to ascertain density).

²⁸⁰ TENN. CODE ANN. § 63-6-245(c) (Supp. 2014).

²⁸¹ See MD. CODE ANN., HEALTH-GEN. § 20-115(c)(1)(ii) (LexisNexis Supp. 2014).

²⁸² See TEX. HEALTH & SAFETY CODE ANN. § 86.013(b) (West Supp. 2014).

As a result, the language used by Tennessee and other states is likely not enough to prevent plaintiff's lawyers from using evidence of violating the statutes as evidence that the physician breached the standard of care. In the minds of the average juror, the standard of care would require physicians to comply with the law. In order to ensure that the density notification statute did not alter malpractice liability, a state would need to bar evidence of violation of the statute. Currently, Texas is the only state that takes this approach. The Texas statute provides that "[t]he information required by this section or evidence that a person violated this section is not admissible in a civil, judicial, or administrative proceeding."²⁸³ By making violation of the statute inadmissible, Texas ensures that the statute will not be used to set the standard of care.

While Texas has effectively addressed liability for physicians, the majority of states have not. In the majority of states, density notification expands the malpractice risk for physicians, specifically for radiologists, because the density notification statutes create a standard of care, and failure to comply with the statute creates potential medical malpractice liability.

2. *Medical Negligence Per Se*

Density notification statutes increase the malpractice risk, not just for simple negligence based malpractice actions, but also by creating a new risk by opening the door to actions based on negligence per se. While medical negligence per se cases are rare, density notification statutes in some states seem to at least open up the possibility of medical negligence per se actions in cases where a patient with dense breasts does not receive a notification. Negligence per se is the legal doctrine, which allows courts to use statutes or administrative regulations to define the standard of care.²⁸⁴ Generally, negligence per se requires that the plaintiff prove the following: (1) violation of a statute or regulation;²⁸⁵ (2) the plaintiff is among the class of people for

²⁸³ *Id.* § 86.013(c).

²⁸⁴ See RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL & EMOTIONAL HARM § 14 (AM. LAW INST. 2010) ("An actor is negligent if, without excuse, the actor violates a statute that is designed to protect against the type of accident the actor's conduct causes, and if the accident victim is within the class of persons the statute is designed to protect.").

²⁸⁵ Most courts do not distinguish between state statutes and local ordinances under the theory that both bodies exercise legislative power on behalf of the state. See, e.g., *Commercial Union Ins. Co. v. Frank Perrotti & Sons, Inc.*, 566 A.2d 431, 434–35 (Conn. App. Ct. 1989); *Combs v. Atlanta Auto Auction, Inc.*, 650 S.E.2d 709, 714 (Ga. Ct. App. 2007) (finding that failure to comply with Fulton County zoning ordinance constituted negligence per se); *Vega v. E. Courtyard Assocs.*, 24 P.3d 219, 221–22 (Nev. 2001) (holding that violation of a building code provision may serve as the basis for an action brought under a negligence per se theory).

whose particular benefit the statute or regulation has been enacted;²⁸⁶ (3) recognition that a private right of action would promote the legislative purpose behind the statute or regulation; and (4) creation of the right would be consistent with the overall legislative scheme.²⁸⁷

The *Restatement (Second) of Torts* provides that the standard of conduct of a reasonable person may be adopted by the court from a legislative enactment or administrative regulation which does not so provide, if (a) the purpose is to protect a class of persons which includes the plaintiff; (b) the purpose of the statute was to guard or protect against the particular interest which is invaded; (c) the purpose of the statute was to protect the plaintiff from the type of harm suffered, and (d) the purpose of the statute was to protect the plaintiff from the particular hazard from which the harm results.²⁸⁸ The *Restatement* goes on to state that “[t]he unexcused violation of a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself.”²⁸⁹

In the case of medical malpractice, the primary difference between simple negligence and negligence per se is the manner by which liability is established. In the normal malpractice case, the plaintiff, through expert testimony, must convince a jury or judge that the physician acted negligently by deviating from the standard of care. The plaintiff with breast cancer would have to prove that the standard of care required the defendant to ascertain that she had dense breast and notify her. This is a daunting task. While the literature tends to show that juries favor physicians²⁹⁰ and that malpractice

²⁸⁶ For example, in *Perry v. S.N.*, the Texas Supreme Court examines five factors when determining whether a violation of statute can be used to establish tort liability: (1) whether the statute is the sole source of any tort duty or whether the statute is based on an existing common law duty; (2) whether the statute puts the public on notice by clearly defining the required conduct; (3) whether the statute imposes liability without fault; (4) whether the imposition of damages would be disproportionate to the seriousness of the statutory violation; and (5) whether the injury to the plaintiff resulted directly or indirectly from the violation of the statute. 973 S.W.2d 301, 307–09 (Tex. 1998).

²⁸⁷ Although courts rarely analyze whether the violation is of a state or federal law, it has been argued that holding that a violation of federal law is negligence per se under state law is simply wrong. See Barbara Kritchevsky, *Tort Law Is State Law: Why Courts Should Distinguish State and Federal Law in Negligence-Per-Se Litigation*, 60 AM. U. L. REV. 71, 74 (2010) (“Finding that a violation of federal law is negligence per se in a state law case allows the federal government to set standards that govern state tort law.”); see also Barbara Kritchevsky, *Whose Idea Was It? Why Violations of State Laws Enacted Pursuant to Federal Mandates Should Not Be Negligence Per Se*, 2009 WIS. L. REV. 693, 696 (arguing that violation of a state law enacted pursuant to a federal mandate should generally not give rise to negligence per se liability).

²⁸⁸ RESTATEMENT (SECOND) TORTS § 286 (AM. LAW INST. 1965).

²⁸⁹ *Id.* § 288B(1); see also *Martin v. Herzog*, 126 N.E. 814, 815 (N.Y. 1920) (“We think the unexcused omission of the statutory signals is more than some evidence of negligence. It is negligence in itself.”).

²⁹⁰ See, e.g., David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2028 (2006) (finding that

plaintiffs have relatively low win rates,²⁹¹ the subjectivity inherent in diagnosing dense breast tissue further tilts the scales in favor of physicians.²⁹² In medical negligence per se cases, the physician's negligence is proven by showing that the physician violated the applicable statute. The remaining issues of proof are limited to showing that the violation of the statute can serve as a basis for negligence per se, cause-in-fact, and proximate cause.

Thus, a breast cancer patient would merely have to prove that the statute required that she be given a notification about her dense breast tissue, that the required notification was not provided, and that she suffered harm as a result of not getting the notification. While not all statutory violations give rise to civil liability under a theory of negligence per se, breast cancer plaintiffs can make a compelling case that negligence per se is appropriate given the fact that the legislature passed the legislation to assure that women would have access to supplemental screenings to catch cancer early.

Some state legislators proactively addressed liability with respect to negligence per se when drafting the breast density notification statutes. Arizona, California, Delaware, Maryland, Nevada, Ohio, Tennessee and Texas incorporated language that is designed to limit civil liability that would arise from violating the density notification statutes.

physicians won 91% of trials in which the medical care had been deemed proper and 57% of cases in which the reviewer found that the physician had erred); Mark I. Taragin et al., *The Influence of Standard of Care and Severity of Injury on the Resolution of Medical Malpractice Claims*, 117 ANNALS INTERNAL MED. 780, 780 (1992) (reviewing 976 malpractice cases and finding that physicians won 79% of the cases that had been rated defensible insurance investigators and 58% of the cases considered indefensible).

²⁹¹ See Peters, *supra* note 254, at 932 ("An expanding body of evidence suggests that jurors begin their deliberations favoring physician-defendants and doubting the motives of plaintiffs in medical malpractice cases.").

²⁹² See Lee, *supra* note 246.

Table 2: *Provisions Designed to Limit Liability*

	Statute does not create or impose liability for failing to comply with the statute or create a new cause of action	Statute should not be construed to create a standard of care or other legal obligation beyond to provide the notice	Statute does not create a cause of action or create a standard of care that provides a basis for a cause of action	Evidence of violation of the statute is inadmissible in any civil proceeding
Alabama				
Arizona	X	X		
California	X	X		
Connecticut				
Delaware			X	X
Hawaii				
Maryland			X	
Massachusetts				
Michigan				
Minnesota				
Missouri				
Nevada		X		
New Jersey				
New York				
N. Carolina				
N. Dakota				
Ohio	X	X		
Oregon				
Pennsylvania				
Rhode Island				
Tennessee	X	X		
Texas			X	X
Virginia				

Ohio's statute is illustrative of the typical approach used by states to limit civil liability for violating the density notification statute. It explicitly states that the density notification requirement does not "[c]reate a new cause of

action or substantive legal right against a person, facility, or other entity.”²⁹³ It further elaborates that the notification law does not “[c]reate a standard of care, obligation, or duty for a person, facility, or other entity that would provide the basis for a cause of action or substantive legal right, other than the duty to send the summary and written report described.”²⁹⁴ Thus, the language used in the Ohio statute along with the similar language used in Delaware,²⁹⁵ Tennessee,²⁹⁶ Nevada,²⁹⁷ Maryland,²⁹⁸ Texas,²⁹⁹ California,³⁰⁰ and Arizona,³⁰¹ effectively forecloses the possibility of plaintiffs bringing a medical negligence per se action. The plain meaning of the statutory language clearly establishes that these density notification statutes were not intended to create a new cause of action. Thus, in Ohio, Tennessee, Nevada, Maryland, Texas, California, Delaware, and Arizona, medical negligence per se is not a viable vehicle for recovery. However, the fifteen other states do not include statutory language that limits civil liability.³⁰² In these states, the state legislators have opened the door to new medical negligence per se claims.

B. *Undermining Physicians*

Traditionally, legislatures and the judiciary have shown unparalleled deference to physicians. From allowing physicians to set the legal standard of care in malpractice cases³⁰³ to adopting the corporate practice of medicine doctrine,³⁰⁴ both the legislature and the judiciary have a long history of

²⁹³ See OHIO REV. CODE ANN. § 3702.40(C)(1) (West Supp. 2015).

²⁹⁴ See *id.* § 3702.40(C)(2).

²⁹⁵ See DEL. CODE ANN. tit. 16, § 3201A (West, Westlaw through 80 Laws 2015, ch. 193).

²⁹⁶ See TENN. CODE ANN. § 63-6-245(c) (Supp. 2014).

²⁹⁷ See NEV. REV. STAT. ANN. § 457.1857(4) (LexisNexis Supp. 2013).

²⁹⁸ See MD. CODE ANN., HEALTH-GEN. § 20-115(c)(1)(ii) (LexisNexis Supp. 2014).

²⁹⁹ See TEX. HEALTH & SAFETY CODE ANN. § 86.013(b) (West Supp. 2014).

³⁰⁰ See CAL. HEALTH & SAFETY CODE § 123222.3(c) (West Supp. 2015).

³⁰¹ See ARIZ. REV. STAT. ANN. § 36-415(B) (Supp. 2014).

³⁰² Alabama, Connecticut, Hawaii, Massachusetts, Michigan, Missouri, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, and Virginia are silent with respect to civil liability.

³⁰³ The Prosser and Keeton hornbook notes that tort law “gives the medical profession . . . the privilege, which is usually emphatically denied to other groups, of setting their own legal standards of conduct, merely by adopting their own practices.” W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 32, at 189 (5th ed. 1984) (footnote omitted).

³⁰⁴ The corporate practice of medicine doctrine prevents persons or other legal entities that are not licensed by the state from providing physician or other medical services or from excessively influencing the delivery of such services. See, e.g., Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX: J. L.-MED. 243, 249–50 (2004) (explaining that “the corporate practice of medicine doctrine prevents persons or entities that are not licensed by the state . . . from

treating physicians more favorably than other professional groups.³⁰⁵ However, the age of deference to physicians has clearly ended.

The winds started changing in the 1950s and 1960s with judges and legislatures forcing doctors to give patients a voice in healthcare decision-making.³⁰⁶ Recently, the shift away from deference to physicians has been dramatic. While the patient autonomy movement forced physicians to share information with their patients, the new regulatory trend is to dictate the content of patient-physician communications. Density notification statutes are one example of this new trend, but there are many.

The most obvious examples relate to the abortion context. After the Supreme Court's decision in *Planned Parenthood of Southeastern Pennsylvania v. Casey*,³⁰⁷ many states enacted informed consent laws.³⁰⁸ Recently Texas,³⁰⁹ North Carolina,³¹⁰ and Oklahoma³¹¹ enacted bills which require physicians to perform ultrasounds and explain the images by providing "the dimensions of the embryo or fetus and the presence of external members and internal organs" before performing an abortion.³¹² These statutes were swiftly challenged in courts by physicians with mixed results.³¹³

In another example of legislators influencing physician-patient communication, Florida implemented legislation that bans physicians from talking with their patients about gun ownership as part of a preventive care

providing physician or other medical services or from excessively influencing the delivery of those services").

³⁰⁵ Physicians have historically enjoyed immunity from anti-trust laws. *See, e.g.*, James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459, 1486 (1994) (discussing that "the judicially-created 'state action' doctrine in the antitrust context allows states to substitute their own regulations for the regime of competition envisioned by antitrust law").

³⁰⁶ *See* discussion of patient autonomy and the doctrine of informed consent *supra* Part III.

³⁰⁷ *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992).

³⁰⁸ *See, e.g.*, GA. CODE ANN. § 31-9A-3(4)(A) (2012); IDAHO CODE § 18-609(5) (Supp. 2015); IND. CODE ANN. § 16-34-2-1.1(b) (West 2007); KAN. STAT. ANN. § 65-6709(h) (West Supp. 2014).

³⁰⁹ *See* TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(4)(C) (West Supp. 2014).

³¹⁰ *See* N.C. GEN. STAT. § 90-21.85(a)(2), (4) (2013).

³¹¹ *See* OKLA. STAT. tit. 63, § 1-738.3d(B)(2), (4) (Supp. 2015).

³¹² N.C. GEN. STAT. ANN. § 90-21.85(a)(4) (2013).

³¹³ The North Carolina statute, the Woman's Right to Know Act, was held unconstitutional by *Stuart v. Camnitz*, 774 F.3d 238, 256 (4th Cir. 2014), finding that forcing physicians to say things they otherwise would not say violated the First Amendment rights of physicians. In *Nova Health Systems v. Pruitt*, 292 P.3d 28, 28–29 (Okla. 2012) (per curiam), the Supreme Court of Oklahoma held that the speech and display requirements were unconstitutional under Supreme Court precedent. In contrast, the Texas statute was deemed constitutional and upheld by the Fifth Circuit Court of Appeals in *Texas Medical Providers Performing Abortion Services v. Lakey*, 667 F.3d 570, 584 (5th Cir. 2012).

discussion.³¹⁴ The Florida law was a response to the American Academy of Pediatrics recommending that pediatricians counsel parents about the dangers of allowing children and adolescents to have access to guns inside and outside of the home.³¹⁵ Similarly, in 2012, California became the first state in the nation to prohibit licensed psychotherapists from engaging in sexual orientation change efforts, such as conversion therapy, for patients under eighteen years of age.³¹⁶ In 2013, New Jersey passed a similar statute.³¹⁷ The California statute was challenged by a host of interested parties including mental health providers who offered conversion therapy. Ultimately, the Ninth Circuit Court of Appeals employed rational basis review and held that the statute was rationally related to the state's legitimate interest in protecting minors and was not facially void for vagueness or overbroad.³¹⁸

With respect to end-of-life communications, California³¹⁹ and New York³²⁰ passed legislation mandating that physicians offer to provide information and patient counseling regarding palliative care and end-of-life options to terminally ill patients. The bills were met with opposition by some physicians who argued that the laws impermissibly intrude into the doctor-patient relationship and fail to appreciate the nuances involved in diagnosing a person as terminally ill.³²¹

Finally, in Pennsylvania, state legislators enacted Act 13, which prevents physicians from disclosing information about chemicals used in the fracking process to patients.³²² Two cases brought by physicians challenging the Act

³¹⁴ Florida's Firearm Owners Privacy Act, FLA. STAT. ANN. § 790.338 (West Supp. 2015), was challenged by physicians and physician advocacy groups on First and Fourteenth Amendment grounds. Although the plaintiffs won at the trial court level, the Eleventh Circuit upheld the law. *See Wollschlaeger v. Governor of Fla.*, 760 F.3d 1195, 1203, 1205 (11th Cir. 2014) (holding that Florida's Firearm Owners Privacy Act does not facially violate the First Amendment).

³¹⁵ AM. ACAD. OF PEDIATRICS COUNCIL ON INJURY, VIOLENCE, & POISON PREVENTION EXEC. COMM., *Policy Statement: Firearm-Related Injuries Affecting the Pediatric Population*, 130 PEDIATRICS e1416, e1421 (2012), <http://pediatrics.aappublications.org/content/early/2012/10/15/peds.2012-2481.full.pdf> [<http://perma.cc/DAF4-WCPC>].

³¹⁶ Sexual orientation change efforts include "efforts to change behaviors or gender expressions, or to eliminate or reduce sexual or romantic attractions or feelings toward individuals of the same sex." CAL. BUS. & PROF. CODE § 865(b)(1) (West Supp. 2015).

³¹⁷ N.J. STAT. ANN. § 45:1-55 (West Supp. 2015).

³¹⁸ *Pickup v. Brown*, 740 F.3d 1208, 1209 (9th Cir. 2014).

³¹⁹ CAL. HEALTH & SAFETY CODE § 442.5 (West Supp. 2015).

³²⁰ Palliative Care Information Act, N.Y. PUB. HEALTH LAW § 2997-c (West 2015).

³²¹ *See, e.g.*, Alan B. Astrow & Beth Popp, *The Palliative Care Information Act in Real Life*, 364 NEW ENG. J. MED. 1885, 1886 (2011); Jane E. Brody, *Law on End-of-Life Care Rankles Doctors*, N.Y. TIMES (June 6, 2011), http://www.nytimes.com/2011/06/07/health/07brody.html?_r=1 [<http://perma.cc/3MTE-DYCH>].

³²² *See* 58 PA. STAT. AND CONS. STAT. ANN. § 3222.1(b)(11) (West Supp. 2015):

If a health professional determines that a medical emergency exists and the specific identity and amount of any chemicals claimed to be a trade secret or

were dismissed for lack of standing.³²³ Collectively, these statutes represent a dangerous trend. This Article does not purport to provide an analysis of the constitutionality of dense breast tissue notification requirements and other attempts to influence the content of patient-physician communications.³²⁴ Since *Casey* affirmed the state's authority to regulate the content of physician-patient communications under the state's licensing authority, this Article assumes that dense breast tissue notification laws are constitutional.³²⁵

However, even though the constitutionality of the density notification provisions cannot seriously be doubted, dense breast tissue notification laws and similar legislation still merit serious reconsideration. The overarching policy question is should state legislators dictate patient-physician communications? The answer is generally no. Legislation that directs physicians to communicate state-mandated messages creates rigid proclamations in a vacuum, which are particularly ill-suited to a field like medicine where small nuances can change the standard of care. When physicians are not communicating their independent expertise and judgment but instead are conveying messages proscribed by the state, the physician-patient relationship is undermined. Americans have long held, albeit at times irrational, fears of government intrusion in healthcare decision-making, and

confidential proprietary information are necessary for emergency treatment, the vendor, service provider or operator shall immediately disclose the information to the health professional upon a verbal acknowledgment by the health professional that the information may not be used for purposes other than the health needs asserted and that the health professional shall maintain the information as confidential.

³²³ See *Rodriguez v. Abruzzo*, 29 F. Supp. 3d 480, 486 (M.D. Pa. 2014); *Rodriguez v. Krancer*, 984 F. Supp. 2d 356, 364 (M.D. Pa. 2013).

³²⁴ A number of scholars have thoroughly analyzed the constitutionality of state regulation of physician speech. See, e.g., Paula Berg, *Toward a First Amendment Theory of Doctor-Patient Discourse and the Right to Receive Unbiased Medical Advice*, 74 B.U. L. REV. 201, 202, 266 (1994) (arguing that compelled speech that is viewpoint neutral is protected, whereas partisan messages about particular treatments or options are unconstitutional); Clay Calvert et al., *Physicians, Firearms & Free Expression: Reconciling First Amendment Theory with Doctrinal Analysis Regarding the Right to Pose Questions to Patients*, 12 FIRST AMEND. L. REV. 1, 62 (2013) (arguing that Florida's Firearm Owner's Privacy Act is an unconstitutional content-based speech regulation); Robert Post, *Informed Consent to Abortion: A First Amendment Analysis of Compelled Physician Speech*, 2007 U. ILL. L. REV. 939, 989-90 (arguing that the First Amendment is not violated by compelled speech mandates as long as physicians retain the right to disagree with or undermine messages that the state wishes to communicate); see also Caroline Mala Corbin, *Compelled Disclosures*, 65 ALA. L. REV. 1277, 1277 (2014) (arguing that it is mandatory abortion counseling laws and not cigarette warnings or crisis pregnancy center disclosures that offend free speech principles).

³²⁵ *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 884 (1992) ("To be sure, the physician's First Amendment rights not to speak are implicated, but only as part of the practice of medicine, subject to reasonable licensing and regulation by the state." (citations omitted)).

these statutes suggest that such fears are warranted.³²⁶ Banning or mandating physician speech is counterproductive and interferes with healthcare decision-making.

In the context of density notification statutes, the legislation is particularly troubling because it is not supported by scientific evidence. As previously discussed, there is nothing objectionable about requiring physicians to give women accurate information about the risk of having dense breasts. However, suggesting follow-up supplemental screenings is very troubling. The American Congress of Obstetricians and Gynecologists does not recommend using additional screening tests for women with dense breasts unless multiple other risk factors are present.³²⁷ Further, the American College of Radiology urges caution “in considering a statutory or legislative mandate to include breast . . . density information in the patient summary.”³²⁸

The medical community does not broadly embrace routine supplemental screenings because there is insufficient data to support their widespread use. Only a few studies have analyzed the effectiveness of supplemental screenings and most have focused on ultrasounds. Recent research from the University of Connecticut School of Medicine at Farmington showed that the state’s dense breast law has resulted in more cancer detection, but noted that the false-positive rate and number of biopsies had also increased.³²⁹ The average cost of each new cancer found was \$110,000.³³⁰ Another study found that using supplemental ultrasound added 1.7 quality adjusted life years at a cost of \$325,000 per year gained.³³¹

Given the lack of controlled reliable data, it is hasty for legislatures to direct women to inquire about supplemental screenings especially because, through that direction, they are creating a climate where physicians feel pressure to order the screenings.³³² A look back at previous treatment fads

³²⁶ Sarah Palin famously expressed this fear when she posted a diatribe entitled “Statement on the Current Health Care Debate” on her Facebook page. In relevant part she writes, “The America I know and love is not one in which my parents or my baby with Down Syndrome will have to stand in front of Obama’s ‘death panel’ so his bureaucrats can decide, based on a subjective judgment . . . whether they are worthy of health care. Such a system is downright evil.” Sarah Palin, *Statement on the Current Health Care Debate*, FACEBOOK (Aug. 7, 2009, 1:26 PM), https://www.facebook.com/note.php?note_id=113851103434 [<https://perma.cc/RSP2-KFCW>].

³²⁷ See Roni Caryn Rabin, *Dense Breasts May Obscure Mammogram Results*, N.Y. TIMES: WELL (June 16, 2014, 4:54 PM), <http://well.blogs.nytimes.com/2014/06/16/dense-breasts-may-obscure-mammogram-results/> [<http://perma.cc/B8M2-VQUW>].

³²⁸ See ACR, *Reporting Breast Density*, *supra* note 141.

³²⁹ See Kathryn L. Greenberg et al., *Ultrasound Screening in Women with Mammographically Dense Breasts*, RADIOLOGICAL SOC’Y N. AM. (Nov. 27, 2011), <http://archive.rsna.org/2011/11007957.html> [<http://perma.cc/N49H-2BCG>].

³³⁰ *Id.*

³³¹ See Sprague et al., *supra* note 202, at 154. The costs decreased to \$246,000 per QALY gained when only screening women with extremely dense breasts. *Id.*

³³² Connecticut and Rhode Island specifically name ultrasounds and MRIs as supplemental screenings that should be discussed with physicians.

suggest that caution is needed. In the 1990s, 41,000 women decided to forgo standard chemotherapy in favor of undergoing high-dose chemotherapy with autologous bone marrow transplant (HDC-ABMT).³³³ At over \$100,000, the procedure was extremely costly.³³⁴ It was also extremely risky³³⁵ with myriad side effects.³³⁶ Many insurers deemed the procedure to be experimental and refused to cover it. So, women sought governmental intervention to assure affordable access. When studies were eventually published that definitively demonstrated the procedure was ineffective, more than 30,000 women had received the treatment, which increased their suffering and shortened their lives at a cost of roughly \$3 billion.³³⁷

In some respects, history can be said to be repeating itself. In addition to efficacy of screenings, recently, mammograms themselves have been sullied. In a study of nearly 90,000 women lasting a quarter of century, researchers found that the death rates from breast cancer were the same in women who received mammograms and those who did not.³³⁸ The study also concluded that one in five cancers found with mammography were treated unnecessarily with chemotherapy, surgery, or radiation.³³⁹ At the same time, screening technologies and recommendations are not static; they are constantly in a state of flux.³⁴⁰ The law charges physicians with the duty of staying abreast of new data, technology, and drugs so that they can adequately apprise patients of their options. When physicians fail to live up to that duty, they can be sued for malpractice. Legislators do not share in that duty to patients. Legislators legislate and then move on to the next issue, leaving physicians to administer

³³³ See Mello & Brennan, *supra* note 33, at 101.

³³⁴ See Patricia C. Kuszler, *Financing Clinical Research and Experimental Therapies: Payment Due, but from Whom?* 3 DEPAUL J. HEALTH CARE L. 441, 458 (2000).

³³⁵ See Geoffrey Cowley et al., *In Pursuit of a Terrible Killer*, NEWSWEEK, Dec. 10, 1990, at 66, 68 (stating that 5–10% of breast cancer recipients die from complications of treatment).

³³⁶ See JoAnne Zujewski et al., *Much Ado About Not . . . Enough Data: High-Dose Chemotherapy with Autologous Stem Cell Rescue for Breast Cancer*, 90 J. NAT'L CANCER INST. 200, 203 (1998).

³³⁷ See Thomas H. Maugh II, *Studies Refute Marrow Procedure for Breast Cancer*, L.A. TIMES (Mar. 11, 2000), <http://articles.latimes.com/2000/mar/11/news/mn-7674> [<http://perma.cc/FK9J-LQMR>].

³³⁸ Anthony B. Miller et al., *Twenty Five Year Follow-up for Breast Cancer Incidence and Mortality of the Canadian National Breast Screening Study: Randomised Screening Trial*, 348 BRITISH MED. J. g366, g366 (2014).

³³⁹ *Id.*

³⁴⁰ For example, the United States Preventative Service Task Force reversed their position on breast self-examination in 2009. The newest recommendations do not recommend breast self-examinations and suggest that women should start screening mammograms at fifty instead of forty. See Gina Kolata, *New Guidelines Suggest Cutback in Mammograms*, N.Y. TIMES (Nov. 17, 2009), <http://query.nytimes.com/gst/fullpage.html?res=9C0DE3DD1338F934A25752C1A96F9C8B63> [<http://perma.cc/GL6Y-G9ZW>]. See Beck, *supra* note 109, for a discussion of new screening technologies.

an unyielding mandated disclosure and navigate any legal pitfalls that the disclosure may create.

Thus, mandating physician communication prevents the communication from being able to adapt to the fluidity of medical breakthroughs. Without the ability to adapt communication, physicians are hamstrung and must waste time talking about issues, which may not be relevant. To the extent they want to know, women should receive unbiased and current information on breast cancer risk and screening options from the best source. The best source is clearly their physician and not state legislators. The inflexible nature of mandates makes them particularly ill-suited for the context of physician–patient communication. As a result, state and federal legislators should avoid enacting legislation that controls the content of physician–patient communication.

V. PROPOSAL FOR AUTONOMY

Lawmakers cannot fix every ill, nor should they try. The breast density notification advocates represent a sliver of constituents. These advocates want more information largely because they have the education to understand and digest the disclosures. They also have the resources to act upon what they learn from their physicians. For the less educated, the disclosure can be unhelpful and confusing.³⁴¹ For the less affluent, being directed to discuss supplemental screenings that you cannot afford (and that may not be covered by insurance) with your physician can cause anxiety and stress.³⁴² When legislating, it is incumbent upon legislatures to conceive of how the problem they are trying to address affects their constituents as a whole. With respect to breast density, legislation should be aimed at improving care for all women.

A. Public Health Recommendation

American women cite breast cancer as their number one personal health fear, notwithstanding the fact that other causes of death claim more women's lives each year.³⁴³ To put breast cancer risk in context, heart disease is the number one killer of American women. It kills roughly 267,000 women a year,

³⁴¹ See, e.g., Mark V. Williams et al., *Inadequate Functional Health Literacy Among Patients at Two Public Hospitals*, 274 JAMA 1677, 1677 (1995) (finding that four of ten patients could not “comprehend directions for taking medication on an empty stomach” and nearly six of ten could not understand the standard informed consent document).

³⁴² See Elisabeth Jacobs, *The Politics of Economic Insecurity* 10 (Issues in Governance Studies No. 10, Sept. 2007), <http://www.brookings.edu/~media/research/files/papers/2007/9/politics-jacobs/jacobs20070913.pdf> [<http://perma.cc/Z9DA-P37D>].

³⁴³ See *Women's Fear of Heart Disease Has Almost Doubled in Three Years, but Breast Cancer Remains Most Feared Disease*, NAT'L HEART, LUNG, & BLOOD INST., <http://www.nhlbi.nih.gov/health/educational/hearttruth/about/fear-doubled.htm> [<http://perma.cc/5YCX-J2AQ>] (last updated Feb. 29, 2012) (reporting that 22.1% of women selected breast cancer and 9.7% selected heart disease).

while breast cancer kills about 40,000.³⁴⁴ Even among cancers, breast cancer ranks second behind lung cancer which kills about 90,000 women each year.³⁴⁵

The stature that breast cancer has in the minds of women is in part due to tremendous physical and emotional toll required to fight the disease.³⁴⁶ However, the stature of breast cancer is also driven by the robust network of organizations dedicated to breast cancer, which have successfully increased awareness of the disease and flooded women with the message that mammograms save lives.³⁴⁷

Despite the fact that almost every woman is aware of breast cancer, there are a host of studies that have examined women's actual understanding of breast cancer including risks,³⁴⁸ screenings,³⁴⁹ and treatment options.³⁵⁰ Generally, these studies have found that women benefit from the use of well-crafted decision-aids, but also that women have widespread misconceptions

³⁴⁴ See *Heart Disease Statistics at a Glance*, GO RED FOR WOMEN, https://www.goredforwomen.org/about-heart-disease/facts_about_heart_disease_in_women-sub-category/statistics-at-a-glance/ [<https://perma.cc/B2K5-FRAT>] (noting that while one in thirty-one American women dies from breast cancer each year, one in three dies of heart diseases, and only one in five American women believe that heart disease is her greatest health threat).

³⁴⁵ See *Lung Cancer Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/cancer/lung/statistics/> [<http://perma.cc/UZS3-FRJ3>] (last updated Aug. 20, 2015) (noting that in 2012, 99,433 women were diagnosed with lung cancer and 70,734 died from lung cancer).

³⁴⁶ See Nurik, *supra* note 5 (noting that she had a double mastectomy with reconstructive surgery and then began chemotherapy, and the side-effects of chemotherapy included "intense fatigue, mouth sores, joint and nerve pain, bloody noses and an extensive list of physical maladies that were simply painful and exhausting[, and it] brought on instantaneous menopause").

³⁴⁷ See Orenstein, *supra* note 23 ("[M]ammography remains an unquestioned pillar of the pink-ribbon awareness movement. Just about everywhere I go—[from] the super market . . . [to] the airport . . . I see posters proclaiming that 'early detection is the best protection' . . .").

³⁴⁸ See generally, e.g., Larissa Nekhlyudov & Ann Partridge, *Breast Cancer Risk Communication: Challenges and Future Research Directions: Workshop Report (United States)*, 14 *CANCER CAUSES & CONTROL* 235 (2003).

³⁴⁹ See, e.g., Gianfranco Domenighetti et al., *Women's Perception of the Benefits of Mammography Screening: Population-Based Survey in Four Countries*, 32 *INT'L J. EPIDEMIOLOGY* 816, 817 (2003); David A. Haggstrom & Marilyn M. Schapira, *Black-White Differences in Risk Perceptions of Breast Cancer Survival and Screening Mammography Benefit*, 21 *J. GEN. INTERNAL MED.* 371, 373 (2006).

³⁵⁰ See, e.g., Collins et al., *supra* note 192, at 519; Angela Fagerlin et al., *An Informed Decision? Breast Cancer Patients and Their Knowledge About Treatment*, 64 *PATIENT EDUC. & COUNSELING* 303, 303 (2006) (finding that "[o]nly 16% of women knew that recurrence rates were different for mastectomy and BCS, and 48% knew that the survival rates were equivalent across treatment"); Katherine A. O'Leary et al., *Information Acquisition for Women Facing Surgical Treatment for Breast Cancer: Influencing Factors and Selected Outcomes*, 69 *PATIENT EDUC. & COUNSELING* 5, 7 (2007).

about breast cancer. One study found that over two-thirds of women believe that mammograms prevent or reduce the risk of contracting breast cancer and that 62% of women believe that screening at least halves breast cancer mortality.³⁵¹ Another study found that 76% of women overestimated mammography screening benefits and 63% underestimated their chances of living five years or longer after a cancer diagnosis.³⁵²

These studies suggest that women would broadly benefit from having better access to information about breast cancer. After a woman has undergone a mammogram and been diagnosed with dense breasts is not the best time to explain the risks associated with dense breasts. At this juncture, her ability to process the information is compromised by worry and anxiety. Thus, giving a woman information about breast density for the first time in a mammographic report is a particularly poor way to advance the goals of promoting autonomous decision-making and improving patient care. Campaigns about breast cancer need to evolve from bringing awareness to conveying actual knowledge.

Public health models typically utilize websites and public service announcements to convey information to the public.³⁵³ These campaigns are typically appealing because they promote individual autonomy by allowing people to use the information as they see fit to do so.³⁵⁴ Assuming that the information disseminated is current and unbiased, a public health model is a better tool for facilitating autonomy. Broad-based education campaigns provide a baseline level of knowledge that a woman can draw from, if she so chooses, when she visits her physician. The role that a woman chooses to have in medical decisions is hers alone to make. Supporting and funding a public health campaign provides information without directing how the information is used. Thus, it is fully compatible with notions of autonomy. In addition, public health advertisements and websites are relatively easy to change to reflect current research. In contrast, the density notification laws are fixed and amendments are subject to what is usually a drawn out legislative process.

The drawbacks to public health campaigns are that conveying complex information is a difficult task. Data and statistics are hard to convey because people interpret chance terms very differently.³⁵⁵ For example, in one study that looked at how patients interpret probability statements researchers found that “[o]nly 80.3% [of research participants] agreed that certain meant 100 of 100 people and only 67.8% agreed that never meant zero of 100 people.”³⁵⁶

³⁵¹ See Domenighetti et al., *supra* note 349, at 816.

³⁵² See Haggstrom & Schapira, *supra* note 349, at 373.

³⁵³ See LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW AND ETHICS 337–38 (Lawrence O. Gostin ed., 1st ed. 2002).

³⁵⁴ *Id.*

³⁵⁵ See Tim Smits & Vera Hoorens, *How Probable is Probably? It Depends on Whom You're Talking About*, 18 J. BEHAV. DECISION MAKING 83, 84 (2005).

³⁵⁶ Kimberley Koons Woloshin et al., *Patients' Interpretation of Qualitative Probability Statements*, 3 ARCHIVES FAM. MED. 961, 965 (1994).

Further, over forty million adults are functionally illiterate and an additional fifty million have marginal literacy skills.³⁵⁷ Thus, there is a chance even well-designed campaigns will fail because a large swath of the population will still be unable to absorb the information presented.

Ultimately, even if a public health campaign fails to successfully reach all women, it still has the benefit of protecting the sanctity of physician–patient communication. There is a tremendous benefit in having physicians communicate freely and confidentially with their patients without worrying about what message the state is requiring them to convey. The proper role of the physician is to focus on the patient and not on state-mandated messaging. Thus, state-sponsored health initiatives allow the state to convey its message while allowing doctors to speak independently.

B. Legislative Recommendations

Dense breast tissue notification laws have noble goals. Namely, they aspire to give women access to information about their breast density so that they can make an informed choice about their healthcare screening options. While this goal is laudable, the path that many legislators have taken to achieve this goal is concerning. Many states have enacted legislation that informs and directs women to act.³⁵⁸ In essence, the ability of women to make an autonomous choice is now being thwarted by the state rather than physicians. Directing and guiding a woman’s healthcare choice does not comport with the patient autonomy movement. For legislators who sincerely believe that legislative action is needed, there are steps that can be taken to ensure that notification statutes inform rather than direct women.

First, legislators should avoid drafting a notification statement that explicitly or implicitly promotes a certain outcome. This means that notification statutes should not direct dense women to “use” the information to talk to her physician³⁵⁹ nor should the statute state that the woman may use the information to engage in shared decision-making with her physician.³⁶⁰ Dense women should be free to decide whether they want to bring up breast density with their physician or not. It is perfectly reasonable for a woman to rely exclusively on her physician’s judgment.

In the breast cancer context, legislation passed under the guise of empowering women has oftentimes undermined women by directing women

³⁵⁷ Ad Hoc Comm. on Health Literacy for the Council on Sci. Affairs, Am. Med. Ass’n, *Health Literacy: Report of the Council on Scientific Affairs*, 281 JAMA 552, 552 (1999).

³⁵⁸ See *supra* Part III.B for a discussion of highly directive and moderately directive approaches to density notification laws.

³⁵⁹ See *supra* Part III.B.1 for an example of highly directive notification statutes.

³⁶⁰ See *supra* Part III.B.2 for an example of moderately directive notification statutes.

towards the preferred choice.³⁶¹ Whether to discuss breast density with a physician and whether to have supplemental screenings are each choices that should be made by women. Thus, secondly, legislators should avoid referring to, or worse still, specifically naming, supplemental screening tests such as ultrasounds or MRIs. Mentioning supplemental screenings suggests that a supplementary screening is or may be necessary. This is quasi-medical advice that is out of sync with the current recommendations of the American Congress of Obstetricians and Gynecologists and the American College of Radiology.³⁶²

Statements which verge on giving medical advice are inappropriate because most legislators lack the training to provide medical advice. In addition, these statements foster a culture of defensive medicine. When patients ask physicians for testing based on information contained in a state-mandated density disclosure, physicians will undoubtedly feel some compulsion to order the supplemental screening tests regardless of whether there is a sufficient scientific basis to warrant utilization. A quarter of state legislators lack college degrees, thus the average legislator is not qualified to give medical advice.³⁶³ As a result, deferring to the recommendations of respected medical bodies like the American Congress of Obstetricians and Gynecologists is the appropriate course of action. When drafting density notification language, the language should convey that dense breast tissue may obscure abnormalities on a mammogram in language that is easy to understand without opining about whether supplementary tests are necessary.

Consequently, it is also premature for states to require insurance coverage of supplemental screenings for dense women. As long as the medical community maintains that such widespread screenings are medically unnecessary, it makes little sense for states to force insurers to require such tests. Supplemental ultrasounds cost hundreds of dollars, while MRIs cost over a thousand dollars. Researchers have put the costs of defensive medicine at over forty billion dollars per year and mandating insurance coverage for supplemental tests will only push this figure higher.³⁶⁴ Thus, legislators should not mandate insurance coverage for supplemental screenings unless a majority of the medical community supports its routine use.

³⁶¹ When states passed breast cancer informed consent statutes in the 1980s many states directed women toward breast-conserving surgery instead of mastectomy because legislators and some advocates believed that it was a better choice. *See* Montini, *supra* note 39, at 91.

³⁶² *See* discussion *supra* Part IV.B.

³⁶³ *See* Scott Smallwood & Alex Richards, *How Educated Are State Legislators?*, CHRON. HIGHER EDUC. (June 12, 2011), <http://chronicle.com/article/How-Educated-Is-Your/127845/> [<http://perma.cc/BN73-2S8S>].

³⁶⁴ *See* Michelle M. Mello et al., *National Costs of the Medical Liability System*, 29 HEALTH AFF. 1569, 1570 (2010) (finding that defensive medicine costs were \$45.59 billion in 2008 dollars).

Third, it is incumbent upon legislators to ensure that the density notification statutes do not increase the number of medical malpractice cases against physicians. Consequently, legislators should make their intentions clear with respect to civil liability. Dense breast tissue notification statutes should explicitly state that it does not create a new cause of action or a standard of care and that violation of the statute is inadmissible in any civil proceeding. Clearly stating this makes it abundantly clear to the plaintiff's bar that violation of the statute will not give rise to liability under a theory of negligence per se.³⁶⁵

Finally, the nature of the legislative process is such that constituents typically lobby to have legislation enacted because they have been harmed by lack of regulation. Once legislation is passed, forces are such that it is rare that a group will lobby to have the legislation repealed. The nature of medical innovation is such that it is changing rapidly. So, even a simple notification that dense breast tissue may obscure cancer on a mammogram may be outdated in a couple of years. To combat the speed of medical advances, dense breast tissue notification statutes should have sunset provisions³⁶⁶ which force legislators to revisit the language after a few years. A few years after implementation, legislators will be able to assess how the mandate is affecting women and physicians. In addition, they will be able to ascertain whether the description of breast density risks still accurately reflects current medical knowledge. In sum, a sunset provision acts as a check to ensure that the mandated risk information does not become outdated and forces legislators to confront whether continued legislation is warranted.

VI. CONCLUSION

For women who are diagnosed with breast cancer, there is no question that times have changed for the better. The collective sense of isolation among breast cancer survivors has been replaced by a robust community of survivors, thrivers, and inspirers. The community of survivors is active. Survivors have been incredibly effective at channeling their resources to advocate for more research, more choices, and better patient-physician communication. Yet, motivated by urgency and the gravitas of their foe (breast cancer), their advocacy is often impetuous and incautious. While dense breast tissue can obscure cancer on mammograms, the quick remedy of sending women a letter and directing them to discuss breast density with their physicians and ask questions about supplemental testing is ill considered.

³⁶⁵ For a discussion of cause of action under a theory of negligence per se, see *supra* Part IV.A.2.

³⁶⁶ Black's Law Dictionary defines "sunset law" as a "statute under which a governmental agency or program automatically terminates at the end of a fixed period unless it is formally renewed." *Sunset Law*, BLACK'S LAW DICTIONARY (10th ed. 2014). The North Dakota density notification statute terminates in 2017. N.D. CENT. CODE § 23-01-43 (Supp. 2015).

Women are not a monolithic group. Early breast cancer advocates mobilized and fought for women to have a voice that was acknowledged, recognized, and respected. The new generation of breast cancer advocates must remember that women are different and that one-size-fits-all problem solving is rarely effective. For legislators considering breast density notification legislation, caution should be exercised. The harm that needs to be remedied should be conceived broadly. Women, generally, lack an understanding about breast cancer risks and the ability of mammograms to detect cancer. While the simplicity of mandates is alluring due to their ease, such mandates are a poor solution to the pervasive lack of understanding about the disease itself.

Hastily enacted density notification statutes can have numerous unintended consequences such as eroding trust between physicians and patients and undermining patient autonomy. The laudable goal of empowering women to make informed healthcare decisions is better achieved through population based public health initiatives rather than targeting individual interactions with physicians. Physicians are bound by professional ethics to use their specialized skills to serve and work for the best interests of their patients. Legislatures should allow physicians to do their jobs without undue interference.

While women can benefit from neutral and truthful information about breast cancer, methods of detection, and breast density, most states have utilized breast density notification statutes to direct and usher women towards questioning their physicians and demanding supplemental cancer screenings. States choosing to enact density legislation should draft neutral notification language, which simply informs women of their density and the limitations of mammography.